IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
Plaintiff,	)	
	)	Civil Action No.: 06-222 JJF
v.	)	
	)	**PUBLIC VERSION**
IMPAX LABORATORIES, INC.,	)	
Defendant.	)	

DECLARATION OF RICHARD K. HERRMANN IN SUPPORT OF DEFENDANT'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No.: 06-222 JJF **FILED UNDER SEAL**

DECLARATION OF RICHARD K. HERRMANN IN SUPPORT OF DEFENDANT'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

I, Richard K. Herrmann, declare:

1. I am an attorney licensed to practice law in the State of Delaware and am a partner in the law firm of Morris James LLP, 500 Delaware Avenue, Suite 1500, Wilmington, Delaware 19801-1494, counsel for Defendant Impax Laboratories, Inc. in the above-captioned action. I am duly admitted to practice law before this Court. Except where expressly stated, I have knowledge of the facts set forth herein, and if called to testify as a witness thereto, could do so competently under oath.

2. Attached hereto as Exhibit Q is a true and correct copy of excerpts from the 30(b)(6) Deposition of Robin Enever, Ph.D.

3. Attached hereto as Exhibit R is a true and correct copy of a Wyeth-Ayerst Research General Technical Report titled, "Development Pharmaceutics Report – Venlafaxine ER."

4. Attached hereto as Exhibit S is a true and correct copy of United States Patent No. 6,274,171 (filed Jan. 20, 2000).

5. Attached hereto as Exhibit T is a true and correct copy of a Memorandum from Dr. R. DeNeale titled "Items of Interest from Venlafaxine Project Team Meeting 7 January 1992."

6. Attached hereto as Exhibit U is a true and correct copy of a document titled "Venlafaxine ER Hydrogel Tablet Work."

7. Attached hereto as Exhibit V is a true and correct copy of Defendant Impax Laboratories, Inc.'s Second Amended Notice of Deposition of Wyeth Pursuant to Fed. R. Civ. P. 30(b)(6).

8. Attached hereto as Exhibit W is a true and correct copy of the Markman Opinion issued on September 6, 2005 in *Wyeth v. Teva Pharmaceuticals USA, Inc.*, United States District Court for the District of New Jersey, Case No. 2:03-CV-1293.

9. Attached hereto as Exhibit X is a true and correct copy of the slip opinion in *Pods, Inc. v. Porta Stor, Inc.*, No. 2006-1504 (Fed. Cir. Apr. 27, 2007).

10. Attached hereto as Exhibit Y is a true and correct copy of Wyeth's Opposition Markman Brief filed in *Wyeth v. Teva Pharmaceuticals USA, Inc.*, United States District Court for the District of New Jersey, Case No. 2:03-CV-1293.

11. Attached hereto as Exhibit Z is a true and correct copy of Wyeth's Opening Markman Brief filed in *Wyeth v. Teva Pharmaceuticals USA, Inc.*, United States District Court for the District of New Jersey, Case No. 2:03-CV-1293.

12. I declare under penalty of perjury under the laws of the state of Delaware that the foregoing is true and correct to the best of my knowledge. Executed this 25th day of May, 2007 at Wilmington, Delaware.

RICHARD K. HERRMANN #405

EXHIBIT Q

ENTIRE EXHIBIT REDACTED

EXHIBIT R

ENTIRE EXHIBIT REDACTED

EXHIBIT S

US006274171B1

(12) **United States Patent**
Sherman et al.

(10) **Patent No.: US 6,274,171 B1**
(45) **Date of Patent: Aug. 14, 2001**

(54) **EXTENDED RELEASE FORMULATION OF VENLAFAXINE HYDROCHLORIDE**

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(73) Assignee: **American Home Products Corporation**, Madison, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/488,629**

(22) Filed: **Jan. 20, 2000**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/964,328, filed on Nov. 5, 1997, now abandoned, which is a continuation-in-part of application No. 08/821,137, filed on Mar. 20, 1997, now abandoned.

(60) Provisional application No. 60/014,006, filed on Mar. 25, 1996.

(51) **Int. Cl.**[7] **A61K 9/52**; A61K 9/54; A61K 9/62

(52) **U.S. Cl.** **424/461**; 424/457; 424/458; 424/459; 514/781; 514/962

(58) **Field of Search** 424/495, 494, 424/461, 458, 459, 457, 456, 462

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,954,959	5/1976	Pedersen	424/21
4,138,475 *	2/1979	McAinsh et al.	424/19
4,369,172	1/1983	Schor et al.	424/19
4,389,393	6/1983	Schor et al.	424/19
4,535,186	8/1985	Husbands et al.	564/336
4,966,768	10/1990	Michelucci et al.	424/468
5,506,270	4/1996	Upton et al.	514/730
5,552,429 *	9/1996	Wong et al.	514/415

FOREIGN PATENT DOCUMENTS

0654264	11/1994	(EP) .
0667150	1/1995	(EP) .
0797991	10/1997	(EP) .
9427589	12/1994	(WO) .
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(57) **ABSTRACT**

This invention relates to a 24 hour extended release dosage formulation and unit dosage form thereof of venlafaxine hydrochloride, an antidepressant, which provides better control of blood plasma levels than conventional tablet formulations which must be administered two or more times a day and further provides a lower incidence of nausea and vomiting than the conventional tablets. More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

25 Claims, No Drawings

EXTENDED RELEASE FORMULATION OF VENLAFAXINE HYDROCHLORIDE

This application continuation-in-part of Application Ser. No. 08/964,328, filed Nov. 5, 1997 abandoned, which is a continuation-in-part of Application Ser. No. 08/821,137, filed Mar. 20, 1997 abandoned, which, in turn, claims priority from Provisional Application No. 60/014,006 filed Mar. 25, 1996.

BACKGROUND OF THE INVENTION

Extended release drug formulations are conventionally produced as compressed tablets by hydrogel tablet technology. To produce these sustained release tablet drug dosage forms, the active ingredient is conventionally compounded with cellulose ethers such as methyl cellulose, ethyl cellulose or hydroxypropylmethylcellulose with or without other excipients and the resulting mixture is pressed into tablets. When the tablets are orally administered, the cellulose ethers in the tablets swell upon hydration from moisture in the digestive system, thereby limiting exposure of the active ingredient to moisture. As the cellulose ethers are gradually leached away by moisture, water more deeply penetrates the gel matrix and the active ingredient slowly dissolves and diffuses through the gel, making it available for absorption by the body. An example of such a sustained release dosage form of the analgesic/anti-inflammatory drug etodolac (Lodine®) appears in U.S. Pat. No. 4,966,768. U.S. Pat. No. 4,389,393 discloses sustained release therapeutic compressed solid unit dose forms of an active ingredient plus a carrier base comprised of a high molecular weight hydroxypropylmethylcellulose, methyl cellulose, sodium carboxymethylcellulose and or other cellulose ether.

Where the production of tablets is not feasible, it is conventional in the drug industry to prepare encapsulated drug formulations which provide extended or sustained release properties. In this situation, the extended release capsule dosage forms may be formulated by mixing the drug with one or more binding agents to form a uniform mixture which is then moistened with water or a solvent such as ethanol to form an extrudable plastic mass from which small diameter, typically 1 mm, cylinders of drug/matrix are extruded, broken into appropriate lengths and transformed into spheroids using standard spheronization equipment. The spheroids, after drying, may then be film-coated to retard dissolution. The film-coated spheroids may then be placed in pharmaceutically acceptable capsules, such as starch or gelatin capsules, in the quantity needed to obtain the desired therapeutic effect. Spheroids releasing the drug at different rates may be combined in a capsule to obtain desired release rates and blood levels. U.S. Pat. No. 4,138,475 discloses a sustained release pharmaceutical composition consisting of a hard gelatin capsule filled with film-coated spheroids comprised of propanolol in admixture with microcrystalline cellulose wherein the film coating is composed of ethyl cellulose, optionally, with hydroxypropylmethylcellulose and/or a plasticizer.

Venlafaxine, 1-[2-dimethylamino)-1-(4-methoxyphenyl) ethyl]cyclohexanol, is an important drug in the neuropharmacological arsenal used for treatment of depression. Venlafaxine and the acid addition salts thereof are disclosed in U.S. Pat. No. 4,535,186. Venlafaxine hydrochloride is presently administered to adults in compressed tablet form in doses ranging from 75 to 350 mg/day, in divided doses two or three times a day. In therapeutic dosing with venlafaxine hydrochloride tablets, rapid dissolution results in a rapid increase in blood plasma levels of the active compound shortly after administration followed by a decrease in blood plasma levels over several hours as the active compound is eliminated or metabolized, until subtherapeutic plasma levels are approached after about twelve hours following administration, thus requiring additional dosing with the drug. With the plural daily dosing regimen, the most common side effect is nausea, experienced by about forty five percent of patients under treatment with venlafaxine hydrochloride. Vomiting also occurs in about seventeen percent of the patients.

BRIEF DESCRIPTION OF THE INVENTION

In accordance with this invention, there is provided an extended release (ER), encapsulated formulation containing venlafaxine hydrochloride as the active drug s component, which provides in a single dose, a therapeutic blood serum level over a twenty four hour period.

Through administration of the venlafaxine formulation of this invention, there is provided a method for obtaining a flattened drug plasma concentration to time profile, thereby affording a tighter plasma therapeutic range control than can be obtained with multiple daily dosing. In other words, this invention provides a method for eliminating the sharp peaks and troughs (hills and valleys) in blood plasma drug levels induced by multiple daily dosing with conventional immediate release venlafaxine hydrochloride tablets. In essence, the plasma levels of venlafaxine Is hydrochloride rise, after administration of the extended release formulations of this invention, for between about five to about eight hours (optimally about six hours) and then begin to fall through a protracted, substantially linear decrease from the peak plasma level for the remainder of the twenty four hour period, maintaining at least a threshold therapeutic level of the drug during the entire twenty-four period. In contrast, the conventional immediate release venlafaxine hydrochloride tablets give peak blood plasma levels in 2 to 4 hours. Hence, in accordance with the use aspect of this invention, there is provided a method for moderating the plural blood plasma peaks and valleys attending the pharmacokinetic utilization of multiple daily tablet dosing with venlafaxine hydrochloride which comprises administering to a patient in need of treatment with venlafaxine hydrochloride, a one-a-day, extended release formulation of venlafaxine hydrochloride.

The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

The formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally,

hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose. Unless otherwise noted, the percentage compositions mentioned herein refer to percentages of the total weight of the final composition or formulation.

More particularly, the extended release formulations of this invention are those above wherein the spheroids are comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 95% microcrystalline cellulose, NF, by weight, and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose, USP, and coated with from about 2% to about 12% of total weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.

A preferred embodiment of this invention are formulations wherein the spheroids are comprised of about 30% to about 40% venlafaxine hydrochloride by weight, about 50% to about 70% microcrystalline cellulose, NF, by weight, and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose, USP, and coated with from about 2% to about 12% of total weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.

Another preferred lower dose formulation of this invention are those wherein the spheroids are comprised less than 30% venlafaxine hydrochloride. These formulations comprise spheroids of from about 6% to about 30% venlafaxine hydrochloride by weight, about 70% to about 94% microcrystalline cellulose, NF, by weight, and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose, USP, and coated with from about 2% to about 12% of total weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.

Within this subgroup of lower dose formulations are formulations in which the spheroids are comprised of from about 6% to about 25% venlafaxine hydrochloride and from about 94% to about 75% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose. Another preferred subgroup of spheroids in these formulations comprises from about 6% to about 25% venlafaxine hydrochloride and from about 94% to about 75% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose. A further preferred subgroup of spheroids in these formulations comprises from about 6% to about 20% venlafaxine hydrochloride and from about 94% to about 80% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose. Within each of these subgroups is understood to be formulations in which the spheroids are comprised of venlafaxine HCl and microcrystalline cellulose in the amounts indicated, with no hydroxypropylmethylcellulose present. Each of these formulations is also preferably contained in a gelatin capsule, preferably a hard gelatin capsule.

DETAILED DESCRIPTION OF THE INVENTION

1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl] cyclohexanol hydrochloride is polymorphic. Of the forms isolated and characterized to date, Form I is considered to be the kinetic product of crystallization which can be converted to Form II upon heating in the crystallization solvent. Forms I and II cannot be distinguished by their melting points but do exhibit some differences in their infrared spectra and X-ray diffraction patterns. Any of the polymorphic forms such as Form I or Form II may be used in the formulations of the present invention.

The extended release formulations of this invention are comprised of 1-[2-(dimethylamino)-1-(4-methoxyphenyl) ethyl]cyclohexanol hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose to provide the desired level of coating, generally from about two to about twelve percent on a weight/weight basis of final product or more preferably from about five to about ten percent (w/w), with best results obtained at from about 6 to about 8 percent (w/w). More specifically, the extended release spheroid formulations of this invention comprise from about 30 to 40 percent venlafaxine hydrochloride, from about 50 to about 70 percent microcrystalline cellulose, NF, from about 0.25 to about I percent hydroxypropylmethylcellulose, USP, and from about 5 to about 10 percent film coating, all on a weight/weight basis. And preferably, the spheroid formulations contain about 35 percent venlafaxine hydrochloride, about 55 to 60 percent microcrystalline cellulose NF (Avicel® PH101), about one half percent hydroxypropylmethylcellulose 2208 USP (K3, Dow, which has a viscosity of 3 cps for 2% aqueous solutions, a methoxy content of 19–24% and a hydroxypropoxy content of 4–13%), and from about 6 to 8 percent film coating.

The film coating is comprised of 80 to 90 percent of ethyl cellulose, NF and 10 to 20 percent hydroxypropylmethylcellulose (2910), USP on a weight/weight basis. Preferably the ethyl cellulose has a ethoxy content of 44.0–51% and a viscosity of 50 cps for a 5% aqueous solution and the hydroxypropylmethylcellulose is USP 2910 having a viscosity of 6 cps at 2% aqueous solution with a methoxy content of 28–30% and a hydroxypropoxy content of 7–12%. The ethyl cellulose used herein is Aqualon HG 2834.

Other equivalents of the hydroxypropylmethylcelluloses 2208 and 2910 USP and ethyl cellulose, NF, having the same chemical and physical characteristics as the proprietary products named above may be substituted in the formulation without changing the inventive concept. Important characteristics of suitable hydroxypropylmethylcelluloses include a low viscosity, preferably less than 10 cps and more preferably 2–5 cps, and a gel temperature above that of the temperature of the extrudate during extrusion. As explained below, these and other characteristics which enable the extrudate to remain moist and soft (pliable) are preferred for the hydroxypropylmethylcellulose. In the examples below, the extrudate temperature was generally 50–55° C.

It was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble. Numerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless because the compressed tablets were either physically unstable (poor compressibility or capping problems) or dissolved too rapidly in dissolution studies. Typically, the tablets prepared as hydrogel sustained release formulations gave 40–50% dissolution at 2 hrs, 60–70% dissolution at 4 hrs and 85–100% dissolution at 8 hrs.

Numerous spheroid formulations were prepared using different grades of microcrystalline cellulose and hydroxypropylmethylcellulose, different ratios of venlafaxine hydrochloride and filler, different binders such as polyvinylpyrrolidone, methylcellulose, water, and polyethylene glycol of different molecular weight ranges in order to find a formulation which would provide a suitable granulation mix which could be extruded properly. In the extrusion process, heat buildup occurred which dried out the extrudate so much that it was difficult to convert the extruded cylinders into spheroids. Addition of hydroxypropylmethylcellulose 2208 to the venlafaxine hydrochloride-microcrystalline cellulose mix made production of spheroids practical.

The encapsulated formulations of this invention may be produced in a uniform dosage for a specified dissolution profile upon oral administration by techniques understood in the art. For instance, the spheroid components may be blended for uniformity with a desired concentration of active ingredient, then spheronized and dried. The resulting spheroids can then be sifted through a mesh of appropriate pore size to obtain a spheroid batch of uniform and prescribed size.

The resulting spheroids can be coated and resifted to remove any agglomerates produced in the coating steps. During the coating process samples of the coated spheroids may be tested for their distribution profile. If the dissolution occurs too rapidly, additional coating may be applied until the spheroids present a desired dissolution rate.

The following examples are presented to illustrate applicant's solution to the problem of preparation of the extended release drug containing formulations of this invention.

EXAMPLE NO. 1

Venlafaxine Hydrochloride Extended Release Capsules

A mixture of 44.8 parts (88.4% free base) of venlafaxine hydrochloride, 74.6 parts of the microcrystalline cellulose, NF, and 0.60 parts of hydroxypropylmethyl cellulose 2208, USP, are blended with the addition of 41.0 parts water. The plastic mass of material is extruded, spheronized and dried to provide uncoated drug containing spheroids.

Stir 38.25 parts of ethyl cellulose, NF, HG2834 and 6.75 parts of hydroxypropylmethylcellulose 2910, USP in a 1:1 v/v mixture of methylene chloride and anhydrous methanol until solution of the film coating material is complete.

To a fluidized bed of the uncoated spheroids is applied 0.667 parts of coating solution per part of uncoated spheroids to obtain extended release, film coated spheroids having a coating level of 3%.

The spheroids are sieved to retain the coated spheroids of a particle size between 0.85 mm to 1.76 mm diameter. These selected film coated spheroids are filled into pharmaceutically acceptable capsules conventionally, such as starch or gelatin capsules.

EXAMPLE NO. 2

Same as for Example 1 except that 1.11 parts of the film coating solution per part of uncoated spheroids is applied to obtain a coating level of 5%.

EXAMPLE NO. 3

Same as for Example 1 except that 1.33 parts of the film coating solution is applied to 1 part of uncoated spheroids to obtain a coating level of 6%.

EXAMPLE NO. 4

Same as for Example 1 except that 1.55 parts of the film coating solution is applied to 1 part of uncoated spheroids to obtain a coating level of 7%.

In the foregoing failed experiments and in Examples 1–4, the extrusion was carried out on an Alexanderwerk extruder. Subsequent experiments carried out on Hutt and Nica extruders surprisingly demonstrated that acceptable, and even improved, spheroids could be made without the use of an hydroxypropylmethylcellulose.

In such further experiments the applicability of the invention was extended to formulations wherein the weight percentage of venlafaxine hydrochloride is 6% to 40%, preferably 8% to 35%. Thus, the extended release spheroid formulations of this invention comprise from about 6 to about 40 percent venlafaxine hydrochloride, from about 50 to about 94 percent microcrystalline cellulose, NF, optionally, from about 0.25 to about 1 percent hydroxypropylmethylcellulose, and from about 2 to about 12 percent, preferably about 3 to 9 percent, film coating.

Spheroids of the invention were produced having 8.25% (w/w) venlafaxine hydrochloride and the remainder (91.75%, w/w) being microcrystalline cellulose, with a coating of from 3 to 5% (w/w), preferably 4%, of the total weight. The spheroids with 8.25% venlafaxine hydrochloride and 4% coating were filled into No. 2 white opaque shells with a target fill weight of 236 mg.

Further spheroids of the invention were produced having 16.5% (w/w) venlafaxine hydrochloride and the remainder (83.5%,w/w) being microcrystalline cellulose, with a coating of from 4 to 6% (w/w), preferably 5%, of the total weight. The spheroids 16.5% venlafaxine hydrochloride and 5% coating were filled into No. 2 white opaque shells with a target fill weight of 122 mg.

The test for acceptability of the coating level is determined by analysis of the dissolution rate of the finished coated spheroids prior the encapsulation. The dissolution procedure followed uses USP Apparatus 1 (basket) at 100 rpm in purified water at 37° C.

Conformance with the dissolution rate given in Table 1 provides the twenty-four hour therapeutic blood levels for the drug component of the extended release capsules of this invention in capsule form. Where a given batch of coated spheroids releases drug too slowly to comply with the desired dissolution rate study, a portion of uncoated spheroids or spheroids with a lower coating level may be added to the batch to provide, after thorough mixing, a loading dose for rapid increase of blood drug levels. A batch of coated spheroids that releases the drug too rapidly can receive additional film-coating to give the desired dissolution profile.

TABLE 1

Acceptable Coated Spheroid Dissolution Rates

Time (hours)	Average % Venlafaxine HCl released
2	<30
4	30–55
8	55–80
12	65–90
24	>80

Batches of the coated venlafaxine hydrochloride containing spheroids which have a dissolution rate corresponding to that of Table 1 are filled into pharmaceutically acceptable

capsules in an amount needed to provide the unit dosage level desired. The standard unit dosage immediate release (IR) tablet used presently provides amounts of venlafaxine hydrochloride equivalent to 25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg venlafaxine. The capsules of this invention are filled to provide an amount of venlafaxine hydrochloride equivalent to that presently used in tablet form and also up to about 150 mg venlafaxine hydrochloride.

Dissolution of the venlafaxine hydrochloride ER capsules is determined as directed in the U. S. Pharmacopoeia (USP) using apparatus 1 at 100 rpm on 0.9 L of water. A filtered sample of the dissolution medium is taken at the times specified. The absorbance of the clear solution is determined from 240 to 450 nanometers (nm) against the dissolution medium. A baseline is drawn from 450 nm through 400 nm and extended to 240 nm. The absorbance at the wavelength of maximum absorbance (about 274 nm) is determined with respect to this baseline. Six hard gelatin capsules are filled with the theoretical amount of venlafaxine hydrochloride spheroids and measured for dissolution. Standard samples consist of venlafaxine hydrochloride standard solutions plus a gelatin capsule correction solution.

The percentage of venlafaxine released is determined from the equation

$$\%\ \text{Venlafaxine hydrochloride released} = \frac{(As)(Wr)(S)(Vl)(0.888)(100)}{(Ar)(V2)(C)}$$

where As is absorbance of sample preparation, Wr is weight of reference standard, mg; S is strength of the reference standard, decimal; V1 is the volume of dissolution medium used to dissolve the dosage form, mL; 0.884 is the percent free base, Ar is the absorbance of the standard preparation, V2 is the volume of reference standard solution, mL; and C is the capsule claim in mg.

Table 2 shows the plasma level of venlafaxine versus time for one 75 mg conventional Immediate Release (IR) tablet administered every 12 hours, two 75 mg extended release (ER) capsules administered simultaneously every 24 hours, and one 150 mg extended release (ER) capsule administered once every 24 hours in human male subjects. The subjects were already receiving venlafaxine hydrochloride according to the dosage protocol, thus the plasma blood level at zero time when dosages were administered is not zero.

TABLE 2

Plasma venlafaxine level (ng/mL) versus time, conventional tablet (not extended release) versus ER capsule

Time (hours)	75 mg (IR)tablet (q 12 h)	2 × 75 mg (ER)capsules (q 24 hr)	1 × 150 mg (ER)capsules (q 24 h)
0	62.3	55.0	55.8
0.5	76.3		
1	135.6	53.3	53.2
2	212.1	69.8	70.9
4	162.0	138.6	133.3
6	114.6	149.0	143.5
8	86.7	129.3	129.5
10		118.4	114.4
12	51.9	105.1	105.8
12.5	74.7		
13	127.5		
14	161.3	90.5	91.3
16	134.6	78.2	78.5
18	106.2		
20	83.6	62.7	63.3
24	57.6	56.0	57.3

Table 2 shows that the plasma levels of two 75 mg/capsule venlafaxine hydrochloride ER capsules and one 150 mg/capsule venlafaxine hydrochloride ER capsule provide very similar blood levels. The data also show that the plasma level after 24 hours for either extended release regimen is very similar to that provided by two immediate release 75 mg tablets of venlafaxine hydrochloride administered at 12 hours intervals.

Further, the plasma levels of venlafaxine obtained with the extended release formulation do not increase to the peak levels obtained with the conventional immediate release tablets given 12 hours apart. The peak level of venlafaxine from (ER), somewhat below 150 ng/ml, is reached in about six hours, plus or minus two hours, based upon this specific dose when administered to patients presently under treatment with venlafaxine hydrochloride (IR). The peak plasma level of venlafaxine, somewhat over 200 ng/ml, following administration of (IR) is reached in two hours and falls rapidly thereafter.

Table 3 shows venlafaxine blood plasma levels in male human subjects having a zero initial blood plasma level. Again, a peak blood plasma concentration of venlafaxine is seen at about 6 hours after dosing with venlafaxine hydrochloride extended release capsules in the quantities indicated. The subjects receiving the single 50 mg immediate release tablet showed a peak plasma level occurring at about 4. hours. For comparative purposes, the plasma levels of venlafaxine for subjects receiving the conventional formulated tablet can be multiplied by a factor of three to approximate the plasma levels expected for a single dose of 150 mg. conventional formulation.

TABLE 3

Plasma Blood Levels in Human Males Having No Prior Venlafaxine Blood Level

Time (Hours)	1 × 50 mg IR tablet	2 × 75 mg ER capsules	1 × 150 mg ER capsule
0	0	0	0
1	27.87	1.3	0
1.5	44.12	6.0	2.2
2	54.83	20.6	12.8
4	66.38	77.0	81.0
6	49.36	96.5	94.4
8	30.06	93.3	86.9
10	21.84	73.2	72.8
12	15.91	61.3	61.4
14	13.73	52.9	51.9
16	10.67	47.5	41.1
20	5.52	35.2	34.0
24	3.56	29.3	28.5
28	2.53	23.4	22.9
36	1.44	11.9	13.5
48	0.66	5.8	5.2

The blood plasma levels of venlafaxine were measured according to the following procedure. Blood samples from the subjects were collected in heparinized evacuated blood tubes and the tubes were inverted gently several times. As

quickly as possible, the tubes were centrifuged at 2500 rpm for 15 minutes. The plasma was pipetted into plastic tubes and stored at −20° C. until analysis could be completed.

To 1 mL of each plasma sample in a plastic tube was added 150 μL of a stock internal standard solution (150 μg/ml). Saturated sodium borate (0.2 mL) solution was added to each tube and vortexed. Five mL of ethyl ether was added to each tube which were then capped and shaken for 10 minutes at high speed. The tubes were centrifuged at 3000 rpm for 5 minutes. The aqueous layer was frozen in dry ice and the organic layer transferred to a clean screw cap tube. A 0.3 mL portion of 0.01 N HCl solution was added to each tube and shaken for 10 minutes at high speed. The aqueous layer was frozen and the organic layer removed and discarded. A 50 μL portion of the mobile phase (23:77 acetonitrile:0.1M monobasic ammonium phosphate buffer, pH 4.4) was added to each tube, vortexed, and 50 μL samples were injected on a Supelco Supelcoil LC-8-DB, 5 cm×4.6 mm, 5 μ; column in a high pressure liquid chromatography apparatus equipped with a Waters Lambda Max 481 detector or equivalent at 229 nm. Solutions of venlafaxine hydrochloride at various concentrations were used as standards.

EXAMPLE NO. 5

Manufactured by the techniques described herein, another preferred formulation of this invention comprises spheroids of from about 30% to about 35% venlafaxine hydrochloride and from about 0.3% to about 0.6% hydroxypropylmethylcellulose. These spheroids are then coated with a film coating, as described above, to a coating level of from about 5% to about 9%, preferably from about 6% to about 8%. A specific formulation of this type comprises spheroids of about 33% venlafaxine hydrochloride and about 0.5% hydroxypropylmethylcellulose, with a film coating of about 7%.

Lower dosage compositions or formulations of this invention may also be produced by the techniques described herein. These lower dosage forms may be administered alone for initial titration or initiation of treatment, prior to a dosage increase. They may also be used for an overall low-dose administration regimen or in combination with higher dosage compositions, such as capsule formulations, to optimize individual dosage regimens.

These lower dose compositions may be used to create encapsulated formulations, such as those containing doses of venlafaxine hydrochloride from about 5 mg to about 50 mg per capsule. Particular final encapsulated dosage forms may include, but are not limited to, individual doses of 7.5 mg, 12.5 mg, 18.75 mg, or 28.125 mg of venlafaxine HCl per capsule.

The spheroids useful in these lower dose formulations may comprise from about 5% to about 29.99% venlafaxine HCl, preferably from about 5% to about 25%, from about 75% to about 95% microcrystalline cellulose, and, optionally from about 0.25% to about 1.0% hydroxypropylmethylcellulose. The spheroids may be coated as described above, preferably with a film coating of from about 5% to about 10% by is weight. In some preferred formulations, the spheroids comprise the cited venlafaxine HCl and microcrystalline cellulose, with no hydroxypropylmethyl cellulose.

EXAMPLE NO. 6

Spheroids comprising 16.5% venlafaxine HCl and 83.5% microcrystalline cellulose were mixed with approximately 50% water (w/w) to granulate in a Littleford Blender Model FM-50E/1Z (Littleford Day Inc., P.O. Box 128, Florence, Ky. 41022-0218, U.S.A.) at a fixed speed of 180 rpm. The blended material was extruded through a 1.25 mm screen using a Nica extruder/speronization machine (Aeromatic-Fielder Division, Niro Inc., 9165 Rumsey Rd., Columbia, Md. 21045, U.S.A.) for a 12/20 mesh cut after drying. Two portions of the resulting spheroids were coated with a 5% and 7% coating level, respectively, by techniques described above using the coating formulation:

Ingredient	% (w/w)
Methylene Chloride	60.000
Methanol Anhydrous	35.500
Ethylcellulose, NF, HG 2834, 50 cps	3.825
Hydroxypropyl Methylcellulose, 2910 USP, 6 cps	0.675

These 5% and 7% coated lots were tested for dissolution on a Hewlett Packard automated dissolution system over a 24 hour period, resulting in the following dissolution patterns

Time/hr	% Dissoluded 16.5%/5%	% Dissolved 16.5%/7%
2	12.4	5.6
4	42.8	25.4
8	70.7	60.4
12	82.2	75.4
24	94.3	92.7

EXAMPLE NO. 7

A formulation of spheroids containing 8.25% venlafaxine HCl and 91.75% microcellulose was prepared according to the techniques of Example No. 6 and coated with a 5% film coating. In the Hewlett Packard automated dissolution system these spheroids provided the following dissolution profile:

Time/hr	% Dissolved 8.25%/5%
2	4.4
4	24.2
8	62.9
12	77.8
24	93.5

Thus, the desired dissolution rates of sustained release dosage forms of venlafaxine hydrochloride, impossible to achieve with hydrogel tablet technology, has been achieved with the film-coated spheroid compositions of this invention.

What is claimed is:

1. An extended release formulation of venlafaxine hydrochloride comprising a pharmaceutically acceptable capsule containing spheroids comprised of from about 6% to about 40% venlafaxine hydrochloride by weight, about 50% to about 94% microcrystalline cellulose, NF, by weight, and optionally from about 0.25% to about 1% by weight of hydroxypropyl-methylcellulose, USP, wherein the spheroids are coated with a film coating composition comprised of ethyl cellulose and hydroxypropylmethylcellulose.

2. An extended release formulation of venlafaxine hydrochloride according to claim 1 which provides peak serum levels of up to 150 ng/ml and extended therapeutically effective plasma levels over a twenty four hour period.

3. An extended release formulation according to claim 1 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.

4. An extended release formulation according to claim 1 wherein the spheroids are comprised of from about 30% to 40% venlafaxine hydrochloride by weight, about 50% to about 70% microcrystalline cellulose, NF, by weight, and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose, USP.

5. An extended release formulation according to claim 4 wherein the spheroids are coated with from about 2% to about 12% of total formulation weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.

6. An extended release formulation according to claim 1 wherein the spheroids comprise from about 6% to about 30% venlafaxine hydrochloride by weight, about 70.1% to about 94% microcrystalline cellulose, NF, by weight and, optionally, from about 0.25% to about 1% by weight of hydroxypropylmethylcellulose.

7. An extended release formulation according to claim 6 wherein the spheroids are coated with from about 2% to about 12% of total weight of film coating comprised of from about 80% to about 90% by weight of film coating of ethyl cellulose, NF, and from about 10% to about 20% by weight of film coating of hydroxypropylmethylcellulose, USP.

8. An extended release formulation according to claim 1 wherein the spheroids comprise from about 5% to about 25% venlafaxine hydrochloride and from about 95% to about 75% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.

9. An extended release formulation according to claim 6 wherein the spheroids comprise from about 6% to about 25% venlafaxine hydrochloride and from about 94% to about 75% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.

10. An extended release formulation according to claim 6 wherein the spheroids comprise from about 6% to about 20% venlafaxine hydrochloride and from about 94% to about 80% microcrystalline cellulose, with an optional amount of from 0.25% to about 1% by weight of hydroxypropylmethylcellulose.

11. An encapsulated, extended release formulation of venlafaxine hydrochloride according to claim 1 having the following dissolution profile in USP Apparatus 1 (basket) at 100 rpm in purified water at 37° C:

Time (hours)	Average % Venlafaxine HCl released
2	<30
4	30–55
8	55–80
12	65–90
24	>80

12. An extended release formulation according to claim 1 wherein the spheroids are composed of about 37% by weight of venlafaxine hydrochloride, about 0.5% by weight of hydroxypropylmethylcellulose, and about 62% by weight of microcrystalline cellulose.

13. An extended release formulation according to claim 1 wherein the film coating is comprised of ethyl cellulose (4.81% of total weight) and hydroxypropylmethylcellulose (0.85% of total weight).

14. An extended release formulation according to claim 1 wherein the film coating comprises 6–8% by weight of total weight.

15. An extended release formulation according to claim 1 wherein the film coating is comprised of ethyl cellulose (2.48% of total weight) and hydroxypropylmethylcellulose (0.437% of total weight).

16. An extended release formulation according to claim 1 wherein the film coating composition is comprised of ethyl cellulose having a 44.0–51.0% content of ethoxy groups and hydroxypropylmethylcellulose having a methoxy content of 28.0–30.0% and a hydroxypropoxy group content of 7.0–12.0%.

17. An extended release formulation according to claim 1 wherein the film coating composition is comprised of about 85% by total weight of film coating of ethyl cellulose having 44.0–51% content of ethoxy groups and about 15% by total weight of film coating of hydroxypropylmethylcellulose having a methoxy content of 28.0–30.0% and a hydroxypropoxy group content of 7.0–12.0%.

18. An extended release formulation according to claim 1 wherein the film coating composition is comprised of 85% by weight of ethyl cellulose having an ethoxy content of 44.0–51% and a viscosity of 50% cps for a 5% aqueous solution, and 15% by weight of hydroxypropylmethylcellulose having a viscosity of 6 cps at 2% aqueous solution with a methoxy content of 28–30% and a hydroxypropoxy content of 7–12%.

19. An extended release formulation of venlafaxine hydrochloride for once daily administration which comprises spheroids containing 37.3% venlafaxine, 62.17% microcrystalline cellulose and 0.5% hydroxypropylmethylcellulose coated with a quantity of a mixture comprised of 85% ethyl cellulose and 15% hydroxypropylmethylcellulose sufficient to give coated spheroids having a dissolution profile in USP Apparatus 1 (basket) at 100 rpm in purified water at 37° C.:

Time	Average % Venlafaxine HCl Released
2	<30
4	30–55
8	55–80
12	65–90
24	>80.

20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides

a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

21. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

22. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

23. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

24. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

25. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

* * * * *

EXHIBIT T

ENTIRE EXHIBIT REDACTED

EXHIBIT U

ENTIRE EXHIBIT REDACTED

EXHIBIT V

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff,	)	
v.	)	Civil Action No.: 06-222 JJF
IMPAX LABORATORIES, INC., Defendant.	)	

DEFENDANT IMPAX LABORATORIES, INC.'S SECOND AMENDED NOTICE OF DEPOSITION OF WYETH PURSUANT TO FED. R. CIV. P. 30(B)(6)

PLEASE TAKE NOTICE that commencing at 9:00 a.m. on April 3, 2007 at the offices of Finnegan Henderson Farabow Garrett & Dunner LLP, 901 New York Ave., N.W., Washington, D.C. 20001, or at another mutually agreed upon time and place, Defendant Impax Laboratories, Inc. ("Impax"), through its attorneys, will take the deposition of Plaintiff Wyeth pursuant to Federal Rule of Civil Procedure 30(b)(6). In advance of the deposition, Wyeth shall designate one or more of its directors, officers, managing agents, or other persons who will testify at the deposition on behalf of Wyeth as to all information known or reasonably available to Wyeth regarding the topics set forth in Schedule A hereto and the definitions in Schedule B. In addition, "(1) the deponent must be knowledgeable on the subject matter identified as the area of inquiry, (2) Wyeth must designate more than one deponent if necessary in order to respond to the relevant areas of inquiry specified by Impax, (3) Wyeth must prepare the witness to testify on matters not only known by the deponent, but those that should be known by Wyeth; and (4) Wyeth must substitute an appropriate deponent when it becomes apparent that the previous deponent is unable to respond to certain relevant

areas of inquiry." 7-30 MOORE'S FEDERAL PRACTICE - CIVIL §30.25 (2006) (quoting *Alexander v. FBI*, 186 F.R.D. 137, 141 (D.D.C. 1998)). The deposition will take place upon oral examination before a notary public or other person authorized to administer oaths, will be recorded by stenographic and/or sound and video means, and will continue from day to day until completed. You are invited to attend and participate.

Dated: April 3, 2007

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SCHEDULE A

DEPOSITION TOPICS

I. WYETH'S ALLEGED CONCEPTION AND REDUCTION TO PRACTICE OF THE ALLEGED "INVENTIONS" IN THE PATENTS

1. FACTS supporting or evidencing WYETH's conception and reduction to practice of the alleged invention(s) claimed in each of the asserted claims of the PATENTS IN SUIT and claim 1 of U.S. Patent No. 6,274,171 B1. (This should be interpreted to include the identity of documents and witnesses as well as when and where those conceptions and reductions to practice took place, who was present and/or participated, what transpired, what DOCUMENTS were authored contemporaneously or near contemporaneously to record what transpired, and the significance of conception and reduction to practice milestones.)

2. Non-privileged information, unless Wyeth knowingly waives privilege, regarding all invention records CONCERNING the asserted claims of the PATENTS IN SUIT and claim 1 of U.S. Patent No. 6,274,171 B1. (This includes without limitation when such records were authored, by whom, pursuant to whose instruction or pursuant to what policy (if any), to whom they were provided, how were they provided, when they were provided, what was the purpose of providing the invention records to such person(s), whether oral communications were contemporaneously or near contemporaneously made with the provision of the records, and where such records are usually kept in the ordinary course of business.)

II. EVOLUTION OF WYETH'S COMMERCIAL PRODUCT -- DEVELOPMENT AND CHARACTERISTICS

3. FACTS relating to the evolution of the composition and formulations of EFFEXOR XR and the development thereof from June 1990 through July 2002. (This should be interpreted to include modification to the formulations during that period, methods of manufacturing, when and where they were developed, who developed them, and what materials and methods were used to develop them). To limit this request further

we are acceding to Wyeth's request to not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.

4. FACTS relating to the *in vitro* and *in vivo* release and bioavailability profiles of EFFEXOR XR from June 1990 through July 2002, including target profiles, when and where those profiles were first achieved, who was involved and oversaw this achievement, and what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles. (EFFEXOR XR should be interpreted to include formulations prepared in the development of WYETH'S commercial EFFEXOR XR™, but excluding hydrogel tablets and gelucire capsules.)

III. WYETH'S FAILURES OF OTHER EXTENDED RELEASE TECHNOLOGIES WITH VENLAFAXINE

A. Hydrogel Tablets

5. The composition of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in *hydrogel tablets*, and its development history from June 1990 through March 1996. (These should be interpreted to include modification to the formulations during that period, methods of manufacturing, when and where those formulations were developed, who developed them, and what materials and methods were used to develop them.) To limit the request further and acceding to Wyeth's request, this does not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.

6. FACTS relating to the *in vitro* and/or *in vivo* release profiles of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in *hydrogel tablets*, from June 1990 through March 1996. (These should be interpreted to include target profiles, when those profiles were first achieved, who was involved and oversaw this achievement, what materials and methods were used to test and achieve

them, modifications to those release profiles, and difficulties in consistently replicating those profiles.)

B. Gelucire Tablets

7. FACTS relating to the composition of EXTENDED RELEASE FORMULATIONS by WYETH comprising VENLAFAXINE in *Gelucire capsules*, and the development thereof from June 1990 through March 1996. (These should be interpreted to include modification to the formulations during that period, methods of manufacturing, when and where those formulations were developed, where they were developed, who developed them, and what materials and methods were used to develop them.) To limit the request further and according to WYETH's request this does not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.

8. FACTS relating to the *in vitro* and/or *in vivo* release profiles of an EXTENDED RELEASE FORMULATIONs by WYETH comprising VENLAFAXINE and Gelucire capsules, from June 1990 through March 1996. (These should be interpreted to include target profiles, when those profiles were first achieved, where they were they achieved, who was involved and oversaw this achievement, what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles.)

IV. OTHER EXTENDED RELEASE FORMULATIONS WHICH MIGHT INVALIDATE THE WYETH PATENTS OR RENDER THEM UNENFORCEABLE

A. Alza Art

9. FACTS relating to the composition and intended use of EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE utilizing ALZA's OROS® oral delivery technology, and the historical development thereof from June 1990 through July 2002. (These should be interpreted to include the formulations' intended use by patients, whether the formulations were expected to provide a therapeutic blood plasma

concentration of VENLAFAXINE over a twenty four hour period with diminished incidences of nausea and emesis, whether the formulations were expected to eliminate the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of VENLAFAXINE, modification to the formulations during that period, methods of manufacturing, when those formulations were developed, where they were developed, who developed them, and what materials and methods were used to develop them). To limit this request further we are acceding to Wyeth's request to not include toxicology, quality control, animal testing, purchasing and qualification of raw materials, or packaging.

10. FACTS relating to the *in vitro* and/or *in vivo* release profiles of an EXTENDED RELEASE FORMULATION by WYETH comprising VENLAFAXINE and utilizing ALZA's OROS® oral delivery technology, from June 1990 through July 2002, including target profiles, when those profiles were first achieved, where they were they achieved, who was involved and oversaw this achievement, what materials and methods were used to test and achieve them, modifications to those release profiles, and difficulties in consistently replicating those profiles.

B. Propranolol and Other Prior Art

11. WYETH's knowledge of the comparison of the solubility of Propranolol to VENLAFAXINE, studies, tests, trials, research, or experiments conducted from June 1990 through July 2002, that compare chemical properties, including without limitation solubility, of propranolol and its salts, with that of VENLAFAXINE and its salts.

V. FACTS EVIDENCING INEQUITABLE CONDUCT BY MISCHARACTERIZING THE CLINICAL STUDIES ON NAUSEA AND FAILURE TO DISCLOSE HIGHLY MATERIAL INFORMATION

12. FACTS showing that the NAMED INVENTORS and persons involved in the prosecution of the PATENTS IN SUIT, were aware of an article by Lynn A. Cunningham, M.D., entitled *Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression*, published in

volume 9, no. 3 of the Annals of Clinical Psychiatry in 1997 prior to and during the prosecution of the PATENTS IN SUIT.

13. The persons at WYETH involved in drafting, reviewing, editing, commenting on, or revising drafts of the article by Lynn A. Cunningham, M.D., entitled *Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression*, published in volume 9, no. 3 of the Annals of Clinical Psychiatry in 1997, including the titles of, job responsibilities of, and reporting structure surrounding those persons.

14. FACTS showing that NAMED INVENTORS and persons involved in the prosecution of the PATENTS IN SUIT, were aware of an article by Richard Entsuah, Ph.D et al, entitled *A Benefit Risk Analysis of Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression*, published in volume 33, no. 4 of the Psychopharmacology Bulletin in 1997 prior to and during the prosecution of the PATENTS IN SUIT.

15. The persons at WYETH involved in drafting, reviewing, editing, commenting on, or revising drafts of the article by Richard Entsuah, Ph.D et al, entitled *A Benefit Risk Analysis of Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression*, published in volume 33, no. 4 of the Psychopharmacology Bulletin in 1997, including the titles of, job responsibilities of, and reporting structure surrounding those persons.

16. FACTS evidencing WYETH's knowledge and research prior to July 2002 demonstrating or refuting that the EXTENDED RELEASE FORMULATION comprising VENLAFAXINE claimed in the PATENTS IN SUIT provided a therapeutic blood plasma concentration of VENLAFAXINE over a twenty-four hour period with diminished incidences of nausea and emesis.

17. FACTS evidencing WYETH's knowledge and research prior to July 2002 demonstrating or refuting that the EXTENDED RELEASE FORMULATION comprising

VENLAFAXINE claimed in the PATENTS IN SUIT eliminated the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of VENLAFAXINE.

VI. FACTS SUPPORTING STATEMENTS IN THE PATENTS OR REQUIRED TO UNDERSTAND THEM; AND PATENT PROSECUTION PRACTICE AND RECORDKEEPING

18. FACTS supporting examples 1 though 7 of the PATENTS IN SUIT, including without limitation the data and experimental records underlying Examples 1 though 7 and DOCUMENTS evidencing that data and experimental records.

19. FACTS supporting tables 1 though 3 of the PATENTS IN SUIT, including without limitation the data underlying Tables 1 through 3 and DOCUMENTS produced by WYETH evidencing that data.

20. The support for, the drafting of, the preparation of, and intended meaning of the following passage of the PATENTS IN SUIT:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

21. The support for, the drafting of, the preparation of, and the intended meaning of the following passage of the PATENTS IN SUIT:

> It was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble.

22. The support for, the drafting of, the preparation of, and intended meaning of the following passage from the Reply Under Rule 111 With Amendment Under

Rule 115 of November 5, 1997 filed with the PTO in U.S. Patent Application, serial no. 08/964,328:

> Moreover, there is a tremendous difference in water solubility of the two compounds. The water solubility of propanolol hydrochloride is 93 mg/ml, whereas that of venlafaxine hydrochloride is 574 mg/ml – i.e. 6 fold greater.

23. WYETH's practices and policies from June 1990 through July 2002 with respect to the prosecution of U.S. patent applications. (This includes the preparation of invention disclosures, evaluation of inventions, performing prior art searches, preparing patent applications, informing inventors of their duty of candor to the Patent Office, gathering and submitting prior art during the course of patent prosecution, evaluation of U.S. Patent and Trademark Office actions and examiner amendments, drafting and review of responses to Office actions, decisions to file provisional, continuation or continuation-in-part applications, and decisions to abandon applications.)

24. WYETH's procedures for collecting and maintaining DOCUMENTS and/or THINGS in their central files, archival or storage locations, and/or kept by individual employees. (This includes without limitation how the DOCUMENTS are organized in central files and/or archival or storage locations, the criteria for whose DOCUMENTS should be or were collected, and what measures are or were taken to ensure that all relevant documents are or were collected in response to requests for DOCUMENTS and THINGS propounded by IMPAX in this action and the defendants in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey.)

25. FACTS and DOCUMENTS CONCERNING the affirmative statements and denials in paragraphs 67 and 68 of WYETH'S REPLY.

VII. WYETH'S NEW DRUG APPLICATION (NDA) AND STATEMENTS MADE TO THE FDA THAT CONTRADICT THE PATENTS AND WYETH'S INTERPRETATION OF THE CLAIMS

26. FACTS evidencing the following parts and contents of NDA No. 20-699 including without limitation any amendments thereto through July 2002:

(a) Integrated Safety Summary

(b) Summary of Human and Pharmacokinetics and Bioavailability

(c) The passage with respect to 600B-144FR stating that that there was "a dissociation between peak venlafaxine concentration and peak nausea. In all treatment conditions the maximum nauseating effect occurred before the time of peak concentration . . . . Compared with venlafaxine CF, the ER formulation, which reached comparable levels with a delayed tmax produced a much less intense maximum effect and a decrease of 63% in the area under the concentration-time curve (AUC) of nausea normalized by dose."

(d) The passage with respect to 600B-144FR stating that that there was "The incidence and severity of nausea would be expected to be less with venlafaxine ER than venlafaxine IR. This conclusion is based on the results of the study 600B-144FR...The incidence of nausea as an adverse event and the severity of nausea, measured as the AUC for a visual analog scale, where lower with venlafaxine ER administration than with venlafaxine IR administration."

VIII. THE ALLEGED COMMERCIAL SUCCESS BY WYETH IS NOT ATTRIBUTABLE TO THE ALLEGED INVENTION BUT TO ADVERTISING AND PROMOTION

A. Advertising, pricing and marketing

27. For the years 1997 through the second quarter of 2006, causes in any fluctuations of, and strategies to maintain or increase, the market share of EFFEXOR XR in the United States.

28. For the years 1997 through the second quarter of 2006, advertising budgets and the content and effectiveness of any advertising and promotional plans and

efforts for EFFEXOR XR in the United States, including without limitation detailing, sampling, and print, radio, and television advertisements, the size of the marketing and sales force, yearly advertising budgets and expenditures.

29. For the years December 2005 to the present, strategies to shift or switch the subscription and/or the consumption of EFFEXOR XR to desvenlafaxine succinate, to be marketed as Pristiq or as another brand name in the United States. (This includes any expected changes in market share of EFFEXOR XR, and any planned print, radio, and television advertisements, the preparation marketing force, rebates, discounts, or changes in pricing pursuant to such strategies.)

30. For the years 1994 through 1998, the content and effectiveness of any advertising and promotional efforts for EFFEXOR in the United States, including without limitation detailing, sampling, and print, radio, and television advertisements, the size of the marketing and sales force, yearly advertising budgets and expenditures.

31. All correspondence with its advertising agencies involved in advertising EFFEXOR and EFFEXOR XR.

B. Revenue, expenses and profitability

32. Revenue, expenses, and profitability for the years 1997 through the second quarter of 2006 from the sale of EFFEXOR XR in the United States, including without sales projections, actual sales, market shares, and profit margins;

SCHEDULE B

DEFINITIONS FOR DEPOSITION TOPICS

When used in the following deposition topics, the following definitions apply:

1. "WYETH" means Plaintiff Wyeth and that company as it was previously named and any related companies, parents, divisions, or subsidiaries, past or present, located in the U.S. or abroad, and the past or present directors, officers, employees, agents, representatives or attorneys thereof.

2. "IMPAX" means Defendant IMPAX Laboratories, Inc. and its past or present directors, officers, employees, agents, representatives or attorneys known to WYETH.

3. "CONCERNING" means referring to, relating to, regarding, comprising, constituting, containing, demonstrating, describing, discussing, evidencing, evincing, evidencing, indicating, on the subject of, on the topic of, showing, or prepared in connection with the stated matter.

4. "DATE" means the exact day, month, and year, if so ascertainable, or if not, the best approximation (including relationship to other events).

5. "DOCUMENT" or "DOCUMENTS" means all written, printed, typed, electronically produced, electronically stored, photostatic, photographed, recorded, or otherwise reproduced communications or records of every kind and description, whether comprised of letters, words, pictures, sounds, symbols, or combinations thereof. DOCUMENTS include originals as well as drafts, copies, marked-up copies, non-identical duplicates, and computer files, including backup or archival copies.

6. "THING" or "THINGS" means any tangible item, including without limitation models, prototypes, research models or samples, and samples of any device or apparatus, or product.

7. "FACTS" includes all evidence including documents concerning thereof, and witnesses knowledgeable of the same.

8. "PERSON" means any natural person, firm, association, organization, partnership, business, trust, corporation, or public entity.

9. "PTO" means the United States Patent and Trademark Office.

10. "FDA" means the United States Food and Drug Administration.

11. "NDA" means New Drug Application.

12. "ANDA" means Abbreviated New Drug Application.

13. "VENLAFAXINE" means the compound 1-[(2-dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexanol commonly known as venlafaxine, as well as all compositions, formulations, and preparations containing venlafaxine, including without limitation VENLAFAXINE and other pharmaceutically acceptable salts of venlafaxine.

14. "EFFEXOR" means the VENLAFAXINE product sold by WYETH as Effexor®.

15. "EFFEXOR XR" means the VENLAFAXINE product sold by WYETH as Effexor® XR.

16. "PATENTS IN SUIT" means U.S. Patent No. 6,274,171 B1, U.S. Patent No. 6,403,120 B1, U.S. Patent No. 6,419,958 B2, and any other patent asserted by WYETH as infringed by IMPAX in the above-captioned action, individually or collectively.

17. "NAMED INVENTORS" means Deborah M. Sherman, John C. Clark, John U. Lamer, Steven A. White, and any other person listed as an inventor for the PATENTS IN SUIT, individually or collectively.

18. For the purposes of this notice only, "EXTENDED RELEASE FORMULATION" means a formulation which releases the active ingredient at a slower

rate than the immediate release formulation of the active ingredient such that the desired dosing frequency is or would be less than that for the immediate release formulation.

19. "WYETH'S REPLY" means the Plaintiff Wyeth's Reply to First Amended Counterclaims of Defendant Impax Laboratories, Inc. filed by WYETH in the above-captioned action on August 30, 2006, and any amendments thereto.

20. "ALZA" means Alza Corporation, and its past or present directors, officers, employees, agents, representatives or attorneys known to WYETH.

CERTIFICATE OF SERVICE

I hereby certify that on April 3, 2007, the foregoing document, DEFENDANT IMPAX LABORATORIES, INC.'S SECOND AMENDED NOTICE OF DEPOSITION OF WYETH PURSUANT TO FED. R. CIV. P. 30(b)(6), was served on counsel via U.S. Mail:

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EXHIBIT W

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH, **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,** **Defendants.**	03-CV-1293 (WJM) **MARKMAN OPINION**

This matter comes before the Court on the parties' submissions seeking construction of four disputed claim terms found in the patents-in-suit. Having taken into consideration the parties' submissions and their arguments made during the *Markman* hearing, the Court construes the disputed claim terms as follows.

BACKGROUND

This is an Abbreviated New Drug Application ("ANDA") patent infringement action. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. ("Teva") filed an ANDA seeking to market a generic version of Wyeth's Effexor® XR. Wyeth filed suit, alleging Teva's generic extended release venlafaxine formulation infringes three of its patents: U.S. Patent Nos. 6,274,171 B1 (the "'171 patent"), 6,419,958 B2 (the "'958 patent"), and 6,403,120 B1 (the "'120 patent"). The three patents are related and share an essentially identical specification.

Wyeth charges Teva with infringement of claims 20-25 of the '171 patent, claims 1-6 of the '958 patent, and claims 1, 2, 13 and 14 of the '120 patent. These claims are all method claims and are directed towards a method of administering an extended release formulation of venlafaxine hydrochloride that provides a therapeutic blood plasma concentration of venlafaxine over twenty-four hours. The specification states that the extended release formulation provides two advantages over the immediate release formulation. First, it eliminates the sharp peaks and troughs in blood plasma drug levels caused by multiple daily dosing with conventional immediate release venlafaxine hydrochloride tablets. '171 patent, col. 2, lines 24-28.[1] Thus, rather than take two to three doses a day, patients need only take the extended release formulation once a day. Second, it reduces the side effects experienced by patients who have taken the immediate release tablets. *See id.* at col. 2, lines 46-55. The extended release formulation was found to reduce the incidence of nausea and emesis (the act of vomiting). According to Wyeth, these two advantages provided improved patient compliance and tolerability, making Effexor® XR a blockbuster drug. (*See* Wyeth's Br. at 2).

Although the named inventors attempted to develop an extended release formulation in the form of a tablet, they failed, finding it "impossible" to achieve a sustained release tablet formulation. Col. 10, lines 53-57. They did, however, succeed in developing a film-coated spheroid formulation that could be administered in a capsule. The specific formulation they found worked was composed of "venlafaxine hydrochloride, microcrystalline cellulose and,

[1]Because the patents-in-suit share an essentially identical specification, all future citations will be to the '171 patent unless otherwise noted.

optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose." Col. 2, line 67 - col. 3, line 2.

Prior to submitting their *Markman* briefs, the Court required the parties to submit a Joint Claim Construction Chart ("Chart") setting forth the claim terms in dispute and the parties' respective proposed constructions for each term. The parties identified four disputed claim terms: "extended release formulations," "spheroid," "with diminished incidence(s) of nausea and emesis," and "encapsulated." (*See* Chart). For claim construction purposes, the following claims are illustrative of how these terms are used. Claims 20 and 21 of the '171 patent recite:

> 20. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 21. A method for eliminating the troughs and peaks of drug concentration in a patients [sic] blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

Claims 1 and 14 of the '120 patent recite:

> 1. A method for providing therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 13. The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid.

DISCUSSION

I. Law of Claim Construction

The Federal Circuit en banc recently reaffirmed the claim construction methodology articulated by *Markman v. Westview Instruments, Inc.*[2] and its progeny and clarified the role that dictionaries play in claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). In *Phillips*, the Federal Circuit reestablished the primacy of the intrinsic evidence – the claims, specification and prosecution history – and reclassified dictionaries as part of the less significant extrinsic evidence. In doing so, the Federal Circuit emphasized the need to construe the claims in their proper context, which is the specification. *Id.* at 1321.

The objective of claim construction is to determine how a person of ordinary skill in the art would understand the claim terms. *Id.* at 1313, 1324. Generally, claim terms are given their ordinary and customary meaning. *Id.* at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). That meaning "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1313. In determining the ordinary meaning of claim terms, the person of ordinary skill in the art is deemed to read the claim terms in the context of the entire patent, including the particular claims in which they appear and the specification. *Id.* at 1313.

The claims "provide substantial guidance as to the meaning of particular claim terms." *Id.* at 1314. Oftentimes, the context in which a term is used in asserted and unasserted claims

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[2] 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996).

"can be highly instructive." *Id.* Further, differences among claims can provide useful insight into a term's meaning. *Id.*

But the claims cannot be looked at in isolation; rather, they must be considered in view of the specification. *Id.* at 1315. The specification is considered to be the "single best guide" for construing the claims. *Id.* The specification may reveal whether the patentee acted as his own lexicographer by giving a claim term a special definition. *Id.* Or, it may show that the patentee intentionally disclaimed claim scope. *Id.* In either case, the patentee's intent is dispositive. *Id.*

A court should also consider the prosecution history, if it is in evidence. *Id.* at 1317. The prosecution history "consists of the complete record of the proceedings before the [Patent and Trademark Office ("PTO")] and includes the prior art cited during the examination of the patent." *Id.* (citing *Autogiro Co. of Am. v. United States*, 181 Ct. Cl. 55, 384 F.2d 391, 399 (1967)). Although it "often lacks the clarity of the specification and thus is less useful for claim construction purposes," the prosecution history sheds light on the PTO's and inventor's understanding of the patent. *Id.*

A court may, in its discretion, consult extrinsic evidence, i.e., dictionaries, treatises, and expert and inventor testimony, when construing claim terms. *Id.* A court may consult extrinsic evidence to educate itself about the field of the invention and to aid its understanding of what one of ordinary skill in the art would understand a claim term to mean. *Id.* at 1319. But extrinsic evidence is "less significant" and "less reliable" than intrinsic evidence because it gives meaning to a claim term in the abstract, rather than in the particular context of the patent. *Id.* at 1317-18. Thus, although it may play a supporting role in claim construction, extrinsic evidence may not be used to contradict an unambiguous meaning established by the intrinsic record. *See id.* at 1324.

II. The Disputed Claim Terms

1. "extended release formulation"

Wyeth contends that "extended release formulation" should be given its ordinary meaning and construed as "[a] formulation which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation." (Chart). Teva asserts that the patentees acted as their own lexicographers by identifying certain ingredients that must be present in the formulation. Teva asserts that "extended release formulation" means "[a] formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration." (*Id.*, emphasis added). Because the Court agrees with Teva that the patentees acted as their own lexicographers, the Court will adopt Teva's proposed claim construction.

The Court begins by looking at the context in which the term "extended release formulation" is used in the claims of the patents-in-suit. Wyeth argues that the asserted claims demonstrate that the patentees did not intend to limit "extended release formulation" to any specific set of ingredients. Every asserted claim recites: "A method . . . which comprises administering orally to a patient in need thereof, an . . . extended release formulation . . ., said formulation containing venlafaxine hydrochloride as the active ingredient." (*See, e.g.*, '171 patent, claim 20, emphasis added). Wyeth argues that if in fact "extended release formulation"

encompassed particular ingredients, including venlafaxine hydrochloride, then the limitation "said formulation containing venlafaxine hydrochloride as the active ingredient" would be superfluous. (Wyeth's Br. at 11). According to Wyeth, if "extended release formulation" already included venlafaxine hydrochloride, then there is no need for the claims to specify the active ingredient. Thus, argues Wyeth, "extended release formulation" does not include any particular ingredients.

Wyeth also contends that the doctrine of claim differentiation supports its broad construction of "extended release formulation." The doctrine of claim differentiation gives rise to a presumption that a limitation added in a dependent claim is not present in the independent claim. *Phillips*, 415 F.3d at 1314-15. Comparing independent claim 1 of the '120 patent with dependent claim 3, Wyeth argues that the doctrine creates a presumption that "extended release formulation" does not include specific ingredients. (Wyeth's Br. at 13). Independent claim 1 recites: "A method . . . which comprises administering orally to a patient in need thereof, an extended release formulation . . ., said formulation containing venlafaxine hydrochloride as the active ingredient." '120 patent, claim 1 (emphasis added). Dependent claim 3 recites: "The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and optionally, hydroxypropylmethylcellulose." '120 patent, claim 3 (emphasis added). Because claim 3 includes the additional limitation of specific ingredients, the Court agrees with Wyeth that a presumption arises that claim 1 does not include that limitation. Thus, the Court agrees with Wyeth that the plain language of the claims implies that "extended release formulation" does not include specific ingredients.

Teva does not dispute that the claims, on their face, imply a broad construction for "extended release formulation." Rather, Teva argues that the presumption the broader construction applies is overcome by the narrow definition given to "extended release formulation" by the patentees in the specification. This Court agrees.

The patentees defined "extended release formulation" several times in the specification. In the abstract, they disclosed:

> More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlfaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent, Abstract. They reiterated this same restrictive definition in the "Brief Description of the Invention:"

> The formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171 patent, col. 2, line 62 - col. 3, line 2. Only after setting forth this description of their invention, did the inventors then go on to address the preferred embodiments of their invention. *See* '171 patent, col. 3, lines 5-62. Similarly, in the "Detailed Description of the Invention," the patentees defined "extended release formulations" by their ingredients:

> The extended release formulations of this invention are comprised of [venlafaxine] hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or

> spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose [sic] to provide the desired level of coating . . . .

'171 patent, col. 4, lines 9-15 (emphasis added).

Wyeth asserts that these statements merely identify a preferred embodiment of the invention. The Court disagrees. Because the specification definitively states that the "extended release formulations" of the invention are limited to particular ingredients, the Court finds that the patentees acted as their own lexicographers and limited the meaning of "extended release formulation." *See Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339-40 (Fed. Cir. 2004) (finding that the inventors acted as their own lexicographers and limited the term "solubilizer" to surfactants by stating in the specification that "[t]he solubilizers suitable according to the invention are defined below", and later describing the suitable solubilizers as surfactants).

Moreover, the specification provides additional support for a narrow construction of "extended release formulation." Although it is improper to limit the claims based on the preferred embodiments, the Federal Circuit has stated that the "preferred embodiments can shed light on the intended scope of the claims." *Id.* at 1340. Here, the specification sets forth seven examples describing different embodiments the named inventors worked with. Each and every embodiment of an "extended release formulation" recited in these examples includes venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC[3] coated with ethyl cellulose and HPMC. *See, e.g.*, '171 patent, col. 5, line 33 - col. 10, line 57. The fact that all of these examples use the same core set of ingredients buttresses the conclusion that "extended release

[3]"HPMC" is the abbreviation for "hydroxypropylmethylcellulose."

formulation" should be narrowly construed. *See Astrazeneca*, 384 F.3d at 1340-41 (finding additional support for a limited construction of "solubilizer" in the fact that "all of the solubilizers listed in the specification and used in the working examples were surfactants").

Further, the specification distinguishes the "extended release formulations" of the invention from extended release hydrogel tablet formulations. Wyeth admits that under its proposed construction, an extended release hydrogel tablet having the claimed *in vivo* characteristics may fall within the asserted claims. (*See* Wyeth's Br. at 16 n.6). The specification, however, discloses that the inventors' attempts to develop extended release hydrogel tablets were "fruitless" and teaches one of ordinary skill that it is "impossible to achieve" the desired dissolution rates using hydrogel tablet technology. Col. 4, lines 60-64; col. 10, lines 53-57. These statements were made without qualification. Accordingly, the specification supports construing "extended release formulation" more narrowly than Wyeth proposes. *See Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000) ("Claims are not correctly construed to cover what was expressly disclaimed.").

Wyeth responds that the specification supports its broader, ordinary meaning of the term. Wyeth asserts that Teva ignores several portions of the specification which allegedly refer only to the "extended release formulation" as including venlafaxine hydrochloride. *See, e.g.*, '171 patent, Abstract ("This invention relates to a 24 hour extended release dosage formulation and unit dosage form thereof of venlafaxine hydrochloride, an antidepressant . . . .") (emphasis added); *Id.* at col. 2, lines 14-16 ("In accordance with this invention, there is provided an extended release (ER), encapsulated formulation containing venlafaxine hydrochloride as the active drug s [sic] component . . . .") (emphasis added); *Id.* at col. 2, lines 37-44 ("Hence, in

accordance with the use aspect of this invention, there is provided a method for moderating the plural blood plasma peaks and valleys . . . which comprises administering to a patient in need of treatment with venlafaxine hydrochloride, a one-a-day, extended release formulation of venlafaxine hydrochloride.") (emphasis added). Wyeth further asserts that its broad construction is supported by those portions of the specification that compare "extended release formulations" with immediate release formulations. *See, e.g.*, '171 patent, col. 2, lines 24-37 (contrasting blood plasma profiles for both types of formulations without reference to specific ingredients). And Wyeth contends that Table 1 in the specification supports a broader construction because it allegedly teaches an ordinary artisan how to screen for other useful inactive ingredients that may work in combination with venlafaxine hydrochloride to develop an extended release venlafaxine formulation. But there is no merit to Wyeth's arguments because they ignore those portions of the specification set forth above that explicitly characterize and limit the invention to a formulation containing specific ingredients.

When the term "extended release formulation" is looked at in its proper context in the specification, this Court believes that one of ordinary skill in the art would construe the term to include specific ingredients. The unequivocal language the patentees used when describing their invention – "the invention comprises an extended release formulation of", "[t]he formulations of this invention comprise" and "[t]he extended formulations of this invention are" – rebuts the presumption established by the doctrine of claim differentiation. *See, e.g., Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1368-69 (Fed. Cir. 2000) (finding the presumption of claim differentiation overcome because the specification and prosecution history described the "protecting back panel" as one that must be relatively stiff). Although this may make certain

dependent claims coterminous and certain claim limitations superfluous, that result is inevitable and inescapable in a case such as this where the patentees act as their own lexicographers. *See Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) ("[T]he doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence."); *Sulé v. Kloehn Co., Ltd.*, 149 F. Supp. 2d 115, 128 (D.N.J. 2001) ("Claim differentiation is a guide, not a rigid rule. If a claim will bear only one interpretation, similarity will have to be tolerated.") (quoting *Autogiro*, 384 F.2d at 404).

The portions of the prosecution history in evidence do not alter this conclusion. Although Wyeth contends that the prosecution history supports a broader construction because the method claims were allowed without limitation to specific ingredients, given the clear and unambiguous language in the specification, the Court believes that the prosecution adds, at most, nothing more than the claims themselves reveal. That being the case, the definition provided by the specification, which is the "single best guide to the meaning of a disputed term," shall be adopted. *Vitronics*, 90 F.3d at 1582.

Because the meaning of the term can be ascertained from the intrinsic record, the Court will not rely on extrinsic evidence that suggests a broader construction. *See Phillips*, 415 F.3d at 1324 (prohibiting the use of extrinsic evidence to contradict the unambiguous meaning provided to a claim term by the intrinsic evidence). That evidence takes the term out of its all-important context in the specification and, thus, will be given no weight.

In sum, "extended release formulation" means "a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC coated with a mixture of ethyl

cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration."

2. "spheroid"

Wyeth contends that "spheroid" means "[o]ne or more particles that are generally shaped like a sphere, although they do not have to be perfectly round", including "granules, beads and pellets." (Chart). Teva asserts that "spheroid" means "[o]ne or more particles that are generally shaped like a sphere and result from an extrusion and spheronization process." (*Id.*, emphasis added). Essentially, although the parties agree that "spheroid" means "one or more particles that are generally shaped like a sphere," they dispute whether the term should be limited to a particular manufacturing process. Because the intrinsic evidence does not narrow the meaning of "spheroids," which connotes shape, the Court will not limit its construction to a specific manufacturing process.

The term "spheroid" is contained in asserted claims 13 and 14 of the '120 patent. Wyeth argues that these claims are drawn broadly to include any "spheroid," regardless of the method of manufacture. Claim 13 recites: "The method of claim 1 wherein the extended release formulation comprising venlafaxine hydrochloride in a spheroid." '120 patent, claim 13 (emphasis added). Claim 14 is similarly broad: "The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid." '120 patent, claim 14 (emphasis added). Thus, the plain language of the claims does not suggest that the term "spheroid" has anything other than its ordinary meaning. Morever, the specification

uses the ordinary meaning of "spheroid," equating "beads" with "spheroids" without any apparent limitation on the method of manufacture. *See* '171 patent, col. 4, lines 12-13 ("Formed as beads or spheroids, the drug containing formulation is coated . . . ."). This ordinary, unrestricted meaning is consistent with how "spheroid" is defined in a dictionary – "[a] body that is shaped like a sphere but is not perfectly round, esp. an ellipsoid that is generated by revolving an ellipse around one of its axes." Am. Heritage College Dict. 1310 (3d ed. 1993).

Teva does not dispute that Wyeth's construction comports with the ordinary meaning of the word "spheroid." (*See* Teva's Opp'n Br. at 23). Rather, it contends that in this case the patents do not support the broader definition because they only identify one method of manufacture – the extrusion and spheronization process. For example, in the "Background of the Invention," the patentees described the process they used for making "spheroids:"

> In this situation, the extended release capsule dosage forms may be formulated by mixing the drug with one or more binding agents to form a uniform mixture which is then moistened with water or a solvent such as ethanol to form an extrudable plastic mass from which small diameter, typically 1 mm, cylinders of drug/matrix are extruded, broken into appropriate lengths and transformed into spheroids using standard spheronization equipment. The spheroids, after drying, may then be film-coated to retard dissolution.

'171 patent, col. 1, lines 38-47 (emphasis added); *see also* col. 5, lines 1-13 (stating that the addition of microcrystalline cellulose and HPMC made manufacture of spheroids with extruders possible); col. 6, lines 6-11 (stating that different extruders allowed spheroids to be made without HPMC).

Teva overreaches. Although the patents disclose only one method of manufacturing "spheroids" – the extrusion and spheronization process – it appears to be described as a preferred

method of manufacture, not the only method of manufacture. *See* '171 patent, col. 1, lines 38-47 (stating that the extended release formulations "may be formulated by" extrusion and spheronization, not must be formulated by this method). Teva appears to be attempting to import the preferred process into the claims. But there is no clear disclaimer of the term's ordinary meaning, nor do the patentees define "spheroid" as being limited to that method of manufacture. Further, the Federal Circuit has held that merely disclosing only one method of manufacture in the specification does not, by itself, limit the term to that one method. *See Vanguard Products Corp. v. Parker Hannifan Corp.*, 234 F.3d 1370, 1371-72 (Fed. Cir. 2000) (construing the word "integral" to define the relationship between layers in a gasket, and refusing to limit the formation of those layers by co-extrusion, the only manufacturing process disclosed in the specification and extolled in the prosecution history); *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1373 (Fed. Cir. 2004).

Teva raises one additional argument to support its narrow construction. It alleges that because the patentees neither described nor enabled the making of "spheroids" by any method other than by extrusion and spheronization, the term "spheroid" should be limited to maintain the validity of claims 13 and 14. (Teva's Br. at 28). Teva notes that the named inventors were aware of other methods of making "spheroids," but did not disclose them to the public. Absent that disclosure, Teva contends that the claims are not enabled or described. This argument is flawed. A court should not construe a claim term to preserve a claim's validity unless, "after applying all the available tools of claim construction," the claim term remains ambiguous. *Liebel-Flarsheim*, 358 F.3d at 911. Here, the term "spheroid" is not ambiguous and, therefore, the Court will not embark on a validity analysis at this time.

In conclusion, the Court finds that "spheroids" should not be limited to a particular method of manufacture. As such, the Court finds that "spheroids" means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round."

3. "with diminished incidence(s) of nausea and emesis"

The parties agree that the meaning of the term "incidence" should include "frequency" of an occurrence or event. (Chart). They disagree, however, whether it should include "degree" or "level." (*See id.*).

The claims that contain this limitation are unilluminating. *See, e.g.*, '171 patent, claims 20, 22-23. Therefore, the Court begins by looking at the specification. Both parties refer to the same passage in the specification to support their construction:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clincial trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

'171 patent, col. 2, lines 45-62 (emphasis added).

Both parties agree that the reference to "level," as used in the above passage, connotes degree. They disagree, however, on what affect, if any, that has on the meaning of "incidence."

Teva contends that the passage above distinguishes between "level," i.e., degree, and "incidence," i.e., frequency. Teva further points out that the claims do not use level or degree; rather, they only refer to "incidence." Wyeth contends that the passage equates "incidence" with "level," thereby broadening the meaning of the term to include degree. Wyeth also juxtaposes the above passage with an excerpt that appears earlier in the specification:

> With the plural daily dosing regimen, the most common side effect is nausea, experienced by about forty five percent of patients under treatment with venlafaxine hydrochloride. Vomiting also occurs in about seventeen percent of the patients.

'171 patent, col. 2, lines 7-11 (emphasis added). Wyeth asserts that this passage demonstrates that when the patentees meant to refer to the number of patients experiencing a side effect, they did so by stating that they were "experienced by" or "occurs in" a certain "percent" of patients. Significantly, according to Wyeth, the patentees did not equate percent with "incidence." Thus, Wyeth asserts "incidence" is broader than frequency.

Wyeth's argument is inapt. Simply because the patentees did not use the word "incidence" in the earlier passage does not by itself redefine "incidence." Rather, that passage makes clear that the patentees were concerned with the number of patients experiencing side effects, not necessarily the severity of those side effects. Moreover, the abstract states that the invention "provides a lower incidence of nausea and vomiting than the conventional tablets." '171 patent, Abstract (emphasis added). Because the only discussion of the conventional tablets in the specification that is relevant to the term "incidence" concerns the percent of patients that experienced side effects, the abstract supports a narrow construction.

Ultimately, Teva appears to be correct that the patentees drew a distinction between "level" and "incidence." Although the specification refers to both terms, the claims only recite "incidence." If indeed "incidence" meant the same thing as "level," or was broader, it begs the question why the word "level" was used in the first place. The reason must be because the patentees meant to differentiate between the two terms. It is clear from the specification that when the patentees wanted to refer to "incidence," they did. Thus, the term "incidence" will be limited to its ordinary meaning as informed by the specification.

Lastly, it is worth noting that "[t]he fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." *Liebel-Flarsheim*, 358 F.3d at 908. Thus, the fact that the patents may discuss a reduced "level" and "incidence" of nausea does not require that claims using the word "incidence" encompass both benefits. In addition, the "incidence" limitation is not present in all of the asserted claims. *See, e.g.*, '171 patent, claims 21, 24-25; '958 patent, claims 2, 5-6. Therefore, to the extent that Wyeth suggests that a narrow construction of this term unjustifiably excludes one of the primary benefits of the invention, namely the reduction in degree of side effects, that is not the case for all asserted claims. The asserted claims that do not contain the "incidence" limitation are obviously broader and would read on such benefits.

Furthermore, to the extent that Wyeth relies on extrinsic evidence to support its broad construction, the Court does not find that evidence particularly helpful. The specification draws a clear distinction between "incidence" and "level." General dictionary definitions that allegedly support a broader construction ignore the context within which the patents use the term. *See,*

e.g., Concise Oxford Dict. of Current English 614 (5th ed. 1964) (defining "incidence" as "range, scope, extent, of influence"). The Federal Circuit in *Phillips* warned of relying on such definitions: "[H]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification." *Phillips*, 415 F.3d at 1321. In any event, other dictionaries define the term as limited to frequency. *See* Webster's Third New Int'l Dict. (Unabridged) 1142 (2002) (defining "incidence" as "rate, range, or amount of occurrence or influence . . . *sometimes*: the rate of occurrence of new cases of a particular disease in a population being studied") (emphasis in original); Taber's Cyclopedic Med. Dict. 1077 (19th ed. 2001) (defining "incidence" as "the frequency of new cases of a disease or condition in a specific population or group"). These dictionaries provide a common meaning that is more fitting given the distinction the specification draws between "incidence" and "level."

Wyeth's experts' opinions, which remove the term "incidence" from its proper context, are also given no weight. *See Phillips*, 415 at 1318 (stating that a court "should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent'") (quoting *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998)). Further, these experts' opinions are countered by Teva's experts, who opine that the common meaning of "incidence" is consistent with only frequency. *See* Schoenfeld Expert Report ¶ 9; Morrow Expert Report ¶ 11.

Accordingly, the Court finds that "with diminished incidence(s) of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to

patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."

4. "encapsulated"

Wyeth asserts that "encapsulated" means "[a] formulation that is present in a capsule, i.e., one that is filled into a pharmaceutically acceptable capsule." (Chart). Teva essentially proposes two different constructions depending on how the Court construes the term "extended release formulation." If the Court construes "extended release formulation" broadly to not include any particular ingredients, Teva contends that "encapsulated" means "[a] formulation that is present in a capsule." (*Id.*). On the other hand, if the Court construes "extended release formulation" to include particular ingredients, Teva agrees with Wyeth's narrower construction. (*See, e.g.*, Teva's Br. at 29 ("If the Court adopts Teva's construction of the term 'extended release formulation,' there is no dispute concerning the term "encapsulated.")).

Although the Court disagrees with Teva's argument that the construction of the term "encapsulated" is contingent on the construction of "extended release formulation," there appears to be no need for this Court to perform an exhaustive analysis of how this term should be construed because the Court has adopted the narrower construction of "extended release formulation." That being the case, the parties do not dispute the meaning of the term "encapsulated." Accordingly, the Court finds that "encapsulated" means "a formulation that is filled into a pharmaceutically acceptable capsule."

CONCLUSION

For the aforementioned reasons, the Court construes the disputed claim terms as follows:

1. "extended release formulation" means "a formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration;"

2. "spheroids" means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round;"

3. "with diminished incidence(s) of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day;"

4. "encapsulated" means "a formulation that is filled into a pharmaceutically acceptable capsule."

Dated: September 6, 2005

s/ William J. Martini
William J. Martini, U.S.D.J.

EXHIBIT X

United States Court of Appeals for the Federal Circuit

2006-1504

PODS, INC.,

Plaintiff-Appellee,

v.

PORTA STOR, INC.,

Defendant-Appellant,

and

CHRISTOPHER E. NEUGUTH,

Defendant.

Richard H. An, Jenner & Block LLP, of New York, New York, argued for plaintiff-appellee. With him on the brief was Joseph Diamante.

Edward P. Dutkiewicz, of Dunedin, Florida, argued for defendant-appellant.

Appealed from: United States District Court for the Middle District of Florida

Judge Mark A. Pizzo

United States Court of Appeals for the Federal Circuit

2006-1504

PODS, INC.,

Plaintiff-Appellee,

v.

PORTA STOR, INC.,

Defendant-Appellant,

and

CHRISTOPHER E. NEUGUTH,

Defendant.

DECIDED: April 27, 2007

Before LOURIE and DYK, Circuit Judges, and O'MALLEY, District Judge.*

DYK, Circuit Judge.

Appellant Porta Stor, Inc. ("Porta Stor") appeals a judgment in favor of appellee PODS, Inc. ("PODS") for, among other things, patent and copyright infringement. We conclude that the district court erred in its patent claim construction; that no literal

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* Honorable Kathleen M. O'Malley, District Judge, United States District Court for the Northern District of Ohio, sitting by designation.

infringement occurred under the correct construction; and that infringement under the doctrine of equivalents is barred by prosecution history estoppel. Therefore, we reverse the judgment of patent infringement. In addition, since we hold that a reasonable jury could have concluded that PODS did not own the asserted copyright, we reverse the district court's grant of judgment as a matter of law on copyright infringement and remand for a new trial on this issue. In other respects, we affirm.

BACKGROUND

I

PODS and Porta Stor are both storage and moving companies that operate by delivering storage containers to customers. After loading the container, the customer either uses it for on-site storage or requests that the container be picked up and transported to warehouse storage or a destination of the customer's choosing.

PODS is the assignee of United States Patent No. 6,071,062 (filed June 6, 2000) ("'062 patent"), which claims an apparatus and method for lifting a storage container from the ground onto a transport vehicle or vice versa. '062 patent col.1 ll.5-10. Claim 1 claims "[a]n apparatus for lifting, handling and transporting a container" that includes, in relevant part:

> a carrier frame including right and left longitudinal elements juxtaposed with the right and left sides, respectively, of the container to be handled and transported, each longitudinal element extending between opposite first and second ends, the carrier frame having front and rear transverse elements juxtaposed with the front and rear ends, respectively, of the container to be handled and transported, each transverse element extending between opposite right and left ends, the left ends of the front and rear elements being adjacent to the first and second ends, respectively, of the left longitudinal element, and the right ends of the front and rear elements being adjacent to the first and second ends, respectively, of the right longitudinal element.

Id. col.6 l.61—col.7 l.11 (emphases added). Claim 1 also requires that "the carrier frame...is capable of being lowered around the container." Id. col.7 ll.31-33 (emphasis added). It is undisputed that claim 1 discloses a four-sided rectangular carrier frame, with the right and left longitudinal elements defining the length of the rectangle and the front and rear elements defining its width.[1] Apparatus claim 32 is identical to claim 1 in

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[1] Claim 1 states in full:

> 1. An apparatus for lifting, handling and transporting a container having right and left sides and front and rear ends, the apparatus comprising:
>
> a carrier frame including right and left longitudinal elements juxtaposed with the right and left sides, respectively, of the container to be handled and transported, each longitudinal element extending between opposite first and second ends, the carrier frame having front and rear transverse elements juxtaposed with the front and rear ends, respectively, of the container to be handled and transported, each transverse element extending between opposite right and left ends, the left ends of the front and rear elements being adjacent to the first and second ends, respectively, of the left longitudinal element, and the right ends of the front and rear elements being adjacent to the first and second ends, respectively, of the right longitudinal element, the carrier frame further including a plurality of generally vertical upright members, each upright member extending between opposite upper and lower ends;
>
> bearing means attached to each upright member lower end, for ground bearing and relative movement of the upright members with the ground;
>
> elevating means for elevating and lowering the carrier frame with respect to the ground;
>
> positioning means connected to the carrier frame for moving and positioning the carrier frame with respect to the container, and for moving and positioning the carrier frame and container together with respect to a transport vehicle having a platform when the container is to be loaded on to and off from said transport vehicle;
>
> supporting means connected to the carrier frame and to the container for supporting the container to the frame; and

all relevant respects.[2] Claim 29 claims "[a] method of lifting, handling and transporting a container on to and off from a transport vehicle." Id. col.10 ll.47-48. Two limitations of claim 29 are relevant to this appeal: "positioning a carrier frame around the container on the transport vehicle platform" and "moving and positioning the carrier frame around the container." Id. col.10 ll.50-51, col.11 ll.29-30.[3]

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means for providing hydraulic power to actuators,

wherein the carrier frame is capable of being elevated to be moved over the container and is capable of being lowered around the container for attaching the carrier frame to the container for subsequent lifting, handling and transporting of the container.

'062 patent col.6 l.61—col.7 l.35.

[2] Claim 32 is the same as claim 1, except with the following additional limitation (also found in dependent claim 5): "the front and rear transverse elements being selectively adjustable in length to allow expansion of the carrier frame to clear a transport vehicle and the container for positioning and contraction of the carrier frame into close juxtaposition with the transport vehicle and the container." '062 patent col. 12, ll. 13-18.

[3] Claim 29 states in full:

29. A method of lifting, handling and transporting a container on to and off from a transport vehicle having a cargo carrying platform, the method comprising the steps of:

positioning a carrier frame around the container on the transport vehicle platform;

releasably attaching the carrier frame to the container;

extending rear and front upright members downward into a ground-engaging position;

elevating the carrier frame with hydraulic means and container above the transport vehicle platform;

expanding the carrier frame with hydraulic means to clear the sides of the transport vehicle platform;

driving the transport vehicle out from under the carrier frame and container;

lowering the carrier frame and container until the container rests upon the ground;

releasing the carrier frame attachment from the container;

activating a steering and mobility means for providing driving power and directional control to wheels at the lower end of the rear upright members;

directing the movement of the carrier frame away from the container;

elevating the carrier frame to an elevation higher than that of the transport vehicle platform;

moving and positioning the carrier frame over the transport vehicle platform;

deactivating the steering and mobility means;

retracting the carrier frame with hydraulic means to align the upright members in close proximity to the transport vehicle platform;

lowering the carrier frame to rest upon the transport vehicle platform;

retracting the upright members upward away from the ground-engaging position so that the transport vehicle is able to transport the carrier frame;

extending the upright members downward into a ground-engaging position;

elevating the carrier frame with hydraulic means above the transport vehicle platform;

expanding the carrier frame with hydraulic means to clear the sides of the transport vehicle platform;

activating a steering and mobility means for providing driving power and directional control to wheels at the lower end of the rear upright members;

II

On September 16, 2004, PODS filed a complaint in the United States District Court for the Middle District of Florida, and later amended it. The amended complaint alleged that Porta Stor's apparatus for lifting, handling, and transporting storage containers—a three-sided structure with two long sides, one shorter side, and an open-end so as to form a u-shape—infringed the '062 patent. PODS also alleged copyright infringement, asserting that Porta Stor copied a rental agreement for portable storage units of which PODS was the copyright owner.

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directing the movement of the carrier frame away from the transport vehicle platform;

moving and positioning the carrier frame around the container;

lowering the carrier frame adjacent to the ground;

releasably attaching the carrier frame to the container;

elevating the carrier frame and container to an elevation higher than that of the transport vehicle platform;

moving and positioning the carrier frame and container over the transport vehicle platform;

deactivating the steering and mobility means;

retracting the carrier frame with hydraulic means to align the upright members in close proximity to the transport vehicle platform;

lowering the carrier frame and container to rest upon the transport vehicle platform; and

retracting the upright members upward away from the ground-engaging position so that the transport vehicle is able to transport the carrier frame and container.

'062 patent col.10 l.47—col.11 l.47.

The parties consented to have the entire proceeding conducted before a magistrate judge. See 28 U.S.C. § 636(c)(1) (2006). On November 10, 2004, the district court issued a preliminary injunction barring Porta Stor from, inter alia, selling or marketing "their method and apparatus for lifting, handling, and transporting a storage container." On appeal we affirmed the grant of a preliminary injunction, finding that "the magistrate judge was correct in holding that Porta Stor's motion did not present sufficient grounds for dissolving the preliminary injunction." PODS, Inc. v. Porta Stor, Inc., 177 Fed. Appx. 73, 75 (Fed. Cir. 2006).

After the final pretrial conference, the district court resolved issues of claim construction. The parties apparently agreed that the terms "carrier frame" and "around" in claims 1 and 32 required "an apparatus that uses a four-sided or rectangular-shaped carrier frame." PODS, Inc. v. Porta Stor, Inc., No. 04-CV-2101, slip op. at 2 (M.D. Fla. June 5, 2006) ("Claim Construction Order"). Porta Stor argued that the terms in claim 29 should be given the same meaning. Id. at 3. Instead, the district court, agreeing with PODS, construed "carrier frame" in claim 29 as "not limited to a four-sided, rectangular shaped frame" and "around" to mean "on all four sides or on less than all four sides." Id. at 4, 9. The district court apparently agreed with PODS's argument that the omission in claim 29 of the detailed description of a four-sided carrier frame found in claim 1 "presumably carries consequences" and that "the carrier frame described in claim 29 is less precise and limited." Id. at 4.

A jury trial began on June 12, 2006. At the close of the evidence, the district court granted judgment of infringement as a matter of law ("JMOL") for PODS on the patent and copyright infringement claims. It found that independent claim 29 of the '062

patent was literally infringed and that independent claims 1 and 32 (and their dependent claims) were infringed under the doctrine of equivalents. The district court also found, as a matter of law, that the '062 patent was not invalid, thus effectively rejecting Porta Stor's affirmative defenses and counterclaims of invalidity. Additionally, the district court found that the PODS rental agreement was "subject to valid copyright protection" and, since "Porta's rental agreement[] is identical to PODS' rental agreement...Porta by its rental agreement has infringed" PODS's copyright. The case was then submitted to the jury, which found that Porta Stor's infringement of the '062 patent was willful and awarded $1500 in damages. The jury concluded that the infringement of the copyright was not willful and awarded no copyright damages, though the court allowed damages in the statutory minimum amount of $750.

The jury also found a willful violation of the Lanham Act, 15 U.S.C. § 1125, but only awarded $1. The jury also found that Porta Stor willfully violated the Florida common law of unfair competition and awarded $15,000. Finally, the jury found a willful violation of the Florida Deceptive and Unfair Trade Practices Act, but awarded no damages.

On June 16, 2006 (the day of the jury verdict), the court entered a judgment ordering Porta Stor to pay PODS a total of $17,251. The court noted in an order accompanying the judgment that it would still consider a motion from PODS to increase the patent damages under 35 U.S.C. § 284. On August 25, 2006, the district court doubled the patent damages and entered a permanent injunction that bars Porta Stor from infringing the '062 patent. On the same day, it also awarded attorney's fees and

expenses to PODS on the patent claim under 35 U.S.C. § 285 (based on willful infringement) but declined to do so on the non-patent claims.

Porta Stor appealed on July 3, 2006.

DISCUSSION

I

We have an obligation to assure ourselves of our jurisdiction before considering the merits of an appeal. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94-95 (1998). This case represents another example of the litigants' failure to address potential problems concerning the finality of the judgment. The district court entered a formal "Judgment in a Civil Case" on June 16, 2006, that appeared to be appealable.[4] However, on August 25, 2006, the court also entered a permanent injunction on the patent claims. Porta Stor filed a notice of appeal on July 3, 2006, from the June 16, 2006, judgment but apparently did not file a notice of appeal from the August 25, 2006 amended judgment.

Under Federal Rule of Appellate Procedure 4(a)(2), "[a] notice of appeal filed after the court announces a decision or order—but before the entry of the judgment or order—is treated as filed on the date of and after the entry." This situation falls within the scope of Rule 4(a)(2). This provision is designed for situations in which "the

[4] While the judgment as to the patent claims was still subject to enhancement of damages (and enhancement was granted on August 25), that possibility did not bar an immediate appeal pursuant to 28 U.S.C. § 1292(c)(2), which gives this court jurisdiction over a judgment of patent infringement that "is final except for an accounting." See Majorette Toys (U.S.) Inc. v. Darda, Inc. U.S.A., 798 F.2d 1390, 1391 (Fed. Cir. 1986) ("[A]n appeal in a patent case can come to this Court under § 1292(c)(2) after validity and infringement are determined but prior to determining damages."). The pending motion for attorney's fees also did not render the judgment non-appealable. See Budinich v. Becton Dickinson & Co., 486 U.S. 196, 202-03 (1988).

unskilled litigant...files a notice of appeal from a decision that he reasonably but mistakenly believes to be a final judgment, while failing to file a notice of appeal from the actual final judgment." Firstier Mortgage Co. v. Investors Mortgage Ins. Co., 498 U.S. 269, 276 (1991). We believe it applies equally where the formal judgment appears to be appealable even though not final. Thus, Porta Stor's premature notice of appeal should be treated as being filed on August 25, 2006, the date that the district court entered the amended judgment. We thus conclude that we have jurisdiction over this appeal.

Because Article III standing is jurisdictional, we must also consider Porta Stor's standing to bring this appeal before considering the merits. Pandrol USA, 320 F.3d at 1367. We conclude that Porta Stor lacks standing to appeal the jury's finding of a violation of the Florida Deceptive and Unfair Trade Practices Act. "[T]he law is well-settled that a party lacks standing to appeal from a judgment by which it is not aggrieved." See Penda Corp. v. United States, 44 F.3d 967, 971 (Fed. Cir. 1994). The district court's judgment in this case did not award damages, an injunction, or attorney's fees based on the Florida statutory claim, nor did PODS seek a declaratory judgment on this claim. Porta Stor has identified no other basis to conclude that it was aggrieved by the district court's judgment, and therefore it lacks standing to appeal the jury's verdict on the Florida Deceptive and Unfair Trade Practices Act. See id. at 972 ("Courts...have not recognized standing to appeal where a party does not seek reversal of the judgment but asks only for review of unfavorable findings.").

II

Addressing the merits, Porta Stor asserts that the district court erred when it granted JMOL on the issue of patent infringement, finding infringement as a matter of law. We review the grant or denial of JMOL without deference. Go Med. Indus. Pty., Ltd. v. Inmed Corp., 471 F.3d 1264, 1272 (Fed. Cir. 2006). Claim construction is a question of law which we review without deference. Cybor Corp. v. FAS Tech., Inc., 138 F.3d 1448, 1455 (Fed. Cir. 1998) (en banc).

A

Porta Stor argues that the district court erred in not construing the phrases "carrier frame" and "around" in claim 29 to have the same meaning as they undisputedly have in claim 1, namely a four-sided rectangular shaped frame that completely surrounds the container on all four sides.

We begin our claim construction analysis with the words of the claims themselves. See Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). We are not limited to considering just the language of claim 29 because "[o]ther claims of the patent in question, both asserted and unasserted, [are] valuable sources of enlightenment as to the meaning of a claim term." Id. at 1314. In this case, the term "carrier frame" in claim 29 also appears in claim 1 where it is specifically described as including "right and left longitudinal elements" adjacent to "front and rear transverse elements." '062 patent col.6 ll.64-65, col.7 ll.1-2. The parties agree that the structure described as a "carrier frame" in claim 1 is "a four-sided or rectangular-shaped carrier frame" that surrounds the container on all sides. Claim Construction Order, slip op. at 2. We apply a "presumption that the same terms appearing in different portions of the

claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims." Fin Control Sys. Pty., Ltd. v. OAM, Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001); see also, e.g., Phillips, 415 F.3d at 1314; Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001). PODS has pointed to no evidence in the specification or the prosecution history that the term "carrier frame" in claim 29 has any meaning other than the uncontested meaning in claim 1. To the contrary, the only embodiments disclosed in the specification are four-sided. Also, as discussed in the next section, during prosecution the Dousset prior art patent was distinguished on the ground that the '062 patent claimed a rectangular-shaped frame, thus suggesting that all claims were limited to a four-sided device. See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995) ("[A]rguments made during prosecution regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary."). We therefore conclude that the term "carrier frame" in claim 29, as in claim 1, requires "a four-sided or rectangular shape." See Claim Construction Order, slip op. at 2.

As PODS itself notes, in a claim that "recites a four-sided 'carrier frame'...placing that four-sided carrier frame 'around the container' would result in 'all four sides' of the carrier frame being 'around' the container." Appellee's Br. at 24-25. Thus, since we construe the term "carrier frame" in claim 29 to require a four-sided structure, we necessarily construe the term "around" to require the frame to be on all sides of the container. This construction is confirmed by the ordinary meaning of "around," which in this context is defined as "along the outer edge or boundary of...on all sides of...so as

to encircle or enclose...about." Webster's Third New International Dictionary 120 (2002) (emphases added).

The second step of the infringement analysis is to compare the accused device to the patented invention (as construed) to determine infringement. PODS "conced[ed] [that] the accused device, which embodies a u-shaped or open-ended carrier frame, does not literally read on" claim 1 because "claim 1 describes an apparatus that uses a four-sided or rectangular-shaped carrier frame." Claim Construction Order, slip op. at 2-3. Since claim 29 also describes a four-sided or rectangular-shaped carrier frame, there can be no dispute that Porta Stor's device does not literally infringe claim 29. Thus, the district court's finding of literal infringement of claim 29 was erroneous.

B

Even if "a product or process...does not literally infringe upon the express terms of a patent claim[, it] may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997). The district court found infringement by equivalents of claims 1 and 32 of the '062 patent. However, "prosecution history estoppel limits the range of equivalents available to a patentee by preventing recapture of subject matter surrendered during prosecution of the patent." Southwall Techs., 54 F.3d at 1579. "[W]here a patent applicant sets forth multiple bases to distinguish between its invention and the cited prior art," "the separate arguments [can] create separate estoppels" as long as the prior art was not distinguished based on the combination of these various grounds. Id. at 1581-83. "To invoke argument-based estoppel...the prosecution history must evince a

clear and unmistakable surrender of subject matter." Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1364 (Fed. Cir. 2006) (internal quotation marks omitted).

We conclude that arguments made by PODS during prosecution bar it from asserting that Porta Stor's device infringed by equivalents. During prosecution, the examiner rejected claim 1 of the '062 patent as obvious in light of the Dousset prior art reference, U.S. Patent No. 3,541,598 ("'598 patent"), and another reference. **[JA 45]** In response, PODS argued that "Applicants' invention is decidedly different from the teachings of the Dousset patent" for three reasons. First, Dousset required specially designed containers, whereas PODS's device was operable with any container. **[JA 64-65]** Second, "[a]s the Examiner acknowledges, the Dousset reference clearly lacks the teachings of the singular rectangular-shaped frame." J.A. at 65 (emphasis added). Third, PODS's invention "teaches uniformity in the handling, lifting and lowering of a container" whereas "the Dousset reference clearly lacks combined elevating and positioning means as thought by the present invention which allows the carrier frame to be elevated and positioned as a rectangular-shaped frame with respect to the container, the vehicle and the ground." J.A. at 65 (emphasis added). The second basis PODS offered for distinguishing Dousset, along with the reference to a rectangular shape in the third basis, clearly and unmistakably shows that PODS limited its claims to a rectangular-based frame and surrendered any claim to a frame that was not rectangular or four-sided. Since PODS offered each argument as a separate basis for distinguishing Dousset, its rectangular-frame argument created a separate estoppel. See Southwall Techs., 54 F.3d at 1582-83.

PODS argues that it was unnecessary to distinguish Dousset on the rectangular-shape ground since the examiner had acknowledged that Dousset "comprises two separate end-fitted units rather than a single rectangular-shaped frame" and relied on another reference to satisfy the rectangular frame limitation of claim 1. J.A. at 45. However, "[c]lear assertions made during prosecution in support of patentability, whether or not actually required to secure allowance of the claim, may also create an estoppel," Southwall Techs., 54 F.3d at 1583, because "[t]he relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter," Conoco, 460 F.3d at 1364 (quoting Cybor, 138 F.3d at 1457). In this case, PODS, in support of its assertion of patentability over Dousset, clearly stated that its claimed frame was rectangular in shape. A competitor would reasonably believe that PODS had surrendered any claim to a frame that was not rectangular or four-sided in shape, such as Porta Stor's three-sided, u-shaped device.

Thus, PODS's arguments during prosecution bar it from asserting that Porta Stor's device infringed claim 1 of the '062 patent under the doctrine of equivalents. Moreover, although the arguments distinguishing Dousset do not directly apply to claim 32, which was added after the obviousness rejection, "once an argument is made regarding a claim term so as to create an estoppel, the estoppel will apply to that term in other claims." Southwall Techs., 54 F.3d at 1584. Therefore, the district court erred in finding claims 1 and 32 infringed under the doctrine of equivalents.[5]

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[5] Although PODS has only asserted literal infringement of claim 29, infringement by equivalents of this claim would be barred by prosecution history estoppel for the same reason. Also, PODS does not argue that any of the Festo

We have no need to consider Porta Stor's arguments related to invalidity, since our finding of non-infringement moots any affirmative defense of invalidity, and Porta Stor has not argued its invalidity counterclaim on appeal.

III

Porta Stor also argues that the district court erred in granting JMOL on copyright infringement. **[BB 38]** "This court applies copyright law as interpreted by the regional circuits," in this case the Eleventh Circuit. Amini Innovation Corp. v. Anthony Cal., Inc., 439 F.3d 1365, 1368 (Fed. Cir. 2006). In the Eleventh Circuit, "[t]he plaintiff...establishes a prima facie case of copyright infringement by proving by a preponderance of the evidence (1) that it owns a valid copyright in the work allegedly infringed, and (2) that the defendant copied that work." M.G.B. Homes, Inc. v. Ameron Homes, Inc., 903 F.2d 1486, 1490 n.7 (11th Cir. 1990) (emphasis in original) (quoting Donald Frederick Evans & Assoc. v. Cont'l Homes, Inc., 785 F.2d 897, 903 (11th Cir. 1986)). The key issue here is ownership.

Ownership of a copyright "vests initially in the author or authors of the work," which is "the party who actually creates the work, that is, the person who translates an idea into a fixed, tangible expression entitled to copyright protection." 17 U.S.C. § 201(a) (2006); see also Cmty. for Creative Non-Violence v. Reid, 490 U.S. 730, 737 (1989) ("CCNV"). However, the statute "carves out an important exception...for 'works made for hire.' If the work is for hire, 'the employer or other person for whom the work was prepared is considered the author' and owns the copyright." CCNV, 490 U.S. at

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exceptions to surrender by amendment should apply in this context. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 740-41 (2002).

737 (quoting 17 U.S.C. § 201(b)). Two types of works can qualify as a "work made for hire":

> (1) a work prepared by an employee within the scope of his or her employment; or
> (2) a work specially ordered or commissioned for use as a contribution to a collective work, as a part of a motion picture or other audiovisual work, as a translation, as a supplementary work, as a compilation, as an instructional text, as a test, as answer material for a test, or as an atlas, if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire.

17 U.S.C. § 101 (2006). In CCNV the Supreme Court explained that "[t]he structure of § 101 indicates that a work for hire can arise through one of two mutually exclusive means, one for employees [the first prong] and one for independent contractors [the second prong]," with the general common law of agency supplying the distinction between employees and independent contractors. 490 U.S. at 742-43. While all works by employees constitute "works made for hire," "only enumerated categories" of works by independent contractors "may be accorded work for hire status" and, even within these categories, only if there is a written instrument designating the work as a work for hire. Id. at 748.

On appeal, PODS does not argue that it owned the copyright under the second prong of § 101, that is, that it succeeded to the copyright interest of its outside counsel. There is as well no evidence that PODS's employees were the sole authors of the agreement. Instead, PODS asserted that "the evidence at trial showed that PODS' employees created the rental agreement at issue with the assistance of an outside lawyer." Appellee's Br. at 48. As best we can understand PODS's argument on appeal, it is asserting co-ownership of a joint work. Under 17 U.S.C. § 201(a), "[t]he authors of

a joint work are coowners of copyright in the work." A "joint work" is "a work prepared by two or more authors with the intention that their contributions be merged into inseparable or interdependent parts of a unitary whole." 17 U.S.C. § 101.

The only evidence at trial on the issue of joint ownership was the testimony of PODS president and CEO Peter Warhurst. On direct examination, Warhurst testified that PODS "went back to the [outside] attorney that helped draft the original mini-storage contract and he...modified it for the uniqueness of...the PODS business." J.A. at 2109 (emphases added). Likewise, when asked whether a document was "the rental agreement that the lawyer developed with your input," Warhurst said "[t]hat's correct." Id. (emphasis added). Similarly, he testified on cross-examination as follows:

> Q: Who wrote the document for you?
> A: The, uh—the lease agreement?
> Q: Yes.
> A: I believe that it was the outside counsel that we had hired.
> ....
> Q: And the attorney who wrote the original document, Mr. Silver—Silverman?
> A: I believe that's who we used at that time, yes.
> Q: He was an attorney who had had [sic] an office, he wasn't an employee of PODS, was he?
> A: Correct.

J.A. at 2130-31 (emphasis added). However, on redirect examination, Warhurst testified as follows:

> Q: You are the president of Pods, Inc.?
> A: I am.
> Q: And...on your executive group are vice-presidents, am I correct?
> A: Yes, sir.
> Q: Would it be fair to say that all of the executive group had some participation in the creation of that unique rental agreement in conjunction with the lawyer?
> A: Uh, my staff and the lawyers worked together to create the document, yes, sir.

J.A. at 2135 (emphasis added).

Warhurst's testimony is inconsistent as to whether the outside counsel was the sole author or whether the outside counsel and PODS employees jointly created the work. It is also unclear as to the extent of the employee contributions. Mere participation in, contributions to, and review of the work of an independent contractor by PODS employees would not necessarily create a joint work. See M.G.B. Homes, 903 F.2d at 1492-93 (finding no co-ownership where home builder reviewed architect's drawings, made suggestions and corrections, and had final approval authority). The evidence is plainly insufficient to warrant JMOL in favor of PODS on the question of joint ownership, and the district court erred in granting JMOL.

The question then becomes whether to direct the award of JMOL in favor of Porta Stor or to remand for a new trial. Despite the somewhat skimpy record as to employee contribution, we cannot say that "a reasonable jury would not have a legally sufficient evidentiary basis to find for [PODS] on [the copyright ownership] issue." Fed. R. Civ. P. 50(a)(1). A jury could have believed that the contributions of the PODS employees were sufficiently significant to find the employees joint authors of the work.

Thus, we conclude that the district court erred in granting JMOL on copyright infringement and that the jury should have been permitted to determine whether PODS had carried its burden to establish ownership of the copyright. We therefore remand the

case to the district court for the limited purpose of holding a new trial on the copyright infringement issue solely on the theory of joint ownership.[6]

CONCLUSION

Under the proper claim construction (requiring a four-sided, rectangular carrier frame), there is no literal infringement of claim 29 of the '062 patent. Since infringement of claims 1 and 32 under the doctrine of equivalents is barred by prosecution history estoppel, we reverse the district court's judgment of infringement and direct it to enter a judgment of non-infringement in favor of Porta Stor. We also reverse the district court's JMOL on copyright infringement and remand to the district court for a new trial limited to the copyright infringement issue. We see no error as to the jury's $1 verdict on the Lanham Act claim or its $15,000 verdict on the Florida common law claim and affirm those parts of the judgment.

AFFIRMED-IN-PART, REVERSED-IN-PART, and REMANDED-IN-PART

COSTS

No costs.

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[6] On appeal, Porta Stor also asserts that JMOL on copyright infringement was erroneous because legal documents are not copyrightable and the copyrighted work was distributed to the public without a copyright notice. The mere fact that the document has a utilitarian purpose does not render it non-copyrightable. See Arthur Rutenberg Homes, Inc. v. Drew Homes, Inc., 29 F.3d 1529, 1533 (11th Cir. 1994) (finding architectural drawings copyrightable). As a general matter, "[t]here appear to be no valid grounds why legal forms such as contracts, insurance policies, pleadings and other legal documents should not be protected under the law of copyright." Melville B. Nimmer & David Nimmer, Nimmer on Copyright § 2.18[E] (2006). And under the current statutory provision (in effect since 1989), notice of the copyright on the document is permissive, not mandatory. See 17 U.S.C. § 401(a); see also Norma Ribbon & Trimming, Inc. v. Little, 51 F.3d 45, 48 (5th Cir. 1995) ("[S]ince the Berne Convention Implementation Act of 1988...notice is no longer a prerequisite to copyright protection." (internal citation omitted)).

EXHIBIT Y

ENTIRE EXHIBIT REDACTED

EXHIBIT Z

ENTIRE EXHIBIT REDACTED

CERTIFICATE OF SERVICE

I hereby certify that on the 30th day of May 2007 I electronically filed the foregoing document, **REDACTED VERSION OF DECLARATION OF RICHARD K. HERRMANN IN SUPPORT OF DEFENDANT'S RESPONSIVE CLAIM CONSTRUCTION BRIEF,** with the Clerk of the Court using CM/ECF which sent notification of such filing to the following:

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